

BEFORE THE  
SCIENTIFIC AND MEDICAL ACCOUNTABILITY  
STANDARDS WORKING GROUP OF THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: LUXE HOTEL  
11461 SUNSET BOULEVARD  
LOS ANGELES, CALIFORNIA

DATE: MAY 3, 2006  
8 A.M.

REPORTER: BETH C. DRAIN, CSR  
CSR. NO. 7152

BRS FILE NO.: 74978

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1           LOS ANGELES, CALIFORNIA; WEDNESDAY, MAY 3, 2006

2

3           CO-CHAIR LO:   FIRST I WANT TO WELCOME  
4   EVERYBODY TO OUR MEETING.  WE HAVE A FULL AND RICH  
5   AGENDA OF IMPORTANT ISSUES TO DISCUSS TODAY.  BUT  
6   FIRST, I WANT TO SAY HELLO AND TO THANK LOS ANGELES  
7   FOR --

8           CO-CHAIR LANSING:  THE RAIN.

9           CO-CHAIR LO:  -- FOR HAVING -- DO WE NEED TO  
10  DO A ROLL CALL FIRST?  SO LET'S FIRST DO A ROLL CALL.

11          MS. ROSAIA:  MARCY FEIT.  BOB KLEIN.  SHERRY  
12  LANSING.

13          CO-CHAIR LANSING:  HERE.

14          MS. ROSAIA:  FRANCISCO PRIETO.

15          DR. PRIETO:  HERE.

16          MS. ROSAIA:  JEFF SHEEHY.  JON SHESTACK.  
17  ALTA CHARO.

18          MS. CHARO:  HERE.

19          MS. ROSAIA:  BERNARD LO.

20          CO-CHAIR LO:  HERE.

21          MS. ROSAIA:  PATRICIA KING.  TED PETERS.

22          MR. PETERS:  HERE.

23          MS. ROSAIA:  KEVIN EGGAN.  ANN KIESSLING.

24          DR. KIESSLING:  HERE.

25          MS. ROSAIA:  JEFFREY KORDOWER.  KENNETH

1 OLDEN.

2 DR. OLDEN: HERE.

3 MS. ROSAIA: JANET ROWLEY. ROBERT TAYLOR.

4 DR. TAYLOR: HERE.

5 MS. ROSAIA: JOHN WAGONER. JAMES WILLERSON.

6 CO-CHAIR LO: IS ZACH ON THE PHONE?

7 MR. LOMAX: ZACH AND KEVIN EGGAN ARE ON THE

8 PHONE.

9 CO-CHAIR LO: KEVIN ANSWERED THE ROLL CALL.

10 MS. ROSAIA: HE DID NOT ANSWER THE ROLL CALL.

11 DO WE HAVE A QUORUM?

12 MR. LOMAX: DO WE HAVE KEVIN EGGAN ON THE

13 LINE?

14 DR. EGGAN: I'M HERE TOO.

15 MR. LOMAX: KEVIN EGGAN IS PRESENT.

16 CO-CHAIR LO: ARE WE EXPECTING JON? ARE WE

17 EXPECTING ANYONE ELSE TO PHONE IN?

18 MR. LOMAX: JOHN WAGONER IS EXPECTED.

19 MS. ROSAIA: HE'S SUPPOSED TO PHONE IN AT

20 NINE. BOB KLEIN IS SUPPOSED TO PHONE IN, JON AND JEFF

21 ARE SUPPOSED TO BE HERE.

22 CO-CHAIR LO: OKAY. SO WHY DON'T WE GO AHEAD

23 AND START. AND I'M GOING TO CALL ON SHERRY TO HELP

24 WITH. CAN YOU FOLKS HEAR US OKAY ON THE PHONE?

25 DR. HALL: GEOFF, WE CAN'T HEAR BERNIE AT

1 ALL.

2 CO-CHAIR LO: OKAY. YOU DIDN'T MISS  
3 ANYTHING. SHERRY IS GOING TO GET TO A MIC. YOU DON'T  
4 NEED TO LISTEN TO ME.

5 CO-CHAIR LANSING: WELL, I ALSO WANT TO  
6 WELCOME ALL OF YOU TO RAINY SOUTHERN CALIFORNIA, WHICH  
7 IS BECOMING MORE NORMAL THAN WE'D LIKE IT TO BE. I  
8 ALSO WANT TO CALL ATTENTION TO ALL OF YOU WHO PERHAPS  
9 DIDN'T KNOW IT, THOUGH I HOPE EVERYBODY DID, ABOUT THE  
10 RESOUNDING POSITIVE COURT VICTORY THAT WE HAD IN OUR  
11 FAVOR, WHICH IS THRILLING AND OBVIOUSLY DUE TO ALL OF  
12 US, AND MAKES THE WORK THAT WE'RE DOING HERE TODAY, NOT  
13 MORE IMPORTANT, BUT MORE TIME SENSITIVE. WE WERE ABLE  
14 TO HAND OUT OUR FIRST TRAINING GRANTS, AND WE WANT THE  
15 SCIENCE TO CONTINUE.

16 I WANT TO THANK THE MEMBERS OF OUR GROUP FOR  
17 THE INORDINATE AMOUNT OF TIME THAT THEY HAVE SPENT IN  
18 THE PAST FEW MONTHS AND IN THE PAST TEN MONTHS. AND I  
19 WANT TO THANK THE MEMBERS OF THE PUBLIC FOR THEIR  
20 COMMENTS, WRITTEN AND ORAL, THAT HAVE HELPED US FORM  
21 THIS GROUP.

22 AS YOU KNOW, WE TURNED OVER OUR REGULATIONS.  
23 BERNIE LO PRESENTED THEM TO THE FULL BOARD OF THE ICOC  
24 ON FEBRUARY 10TH, AND THEY WERE GREETED WITH RESOUNDING  
25 SUCCESS, WHICH STARTED OUR PUBLIC COMMENT PERIOD, WHICH

1 ENDED ON MAY 1ST.

2 THE PURPOSE OF TODAY'S MEETING IS TO ADDRESS  
3 AND PRIORITIZE THE COMMENTS THAT WE RECEIVED FROM THE  
4 PUBLIC. AND WE ARE GOING TO ADDRESS THE ONES THAT  
5 PERTAIN TO OUR GROUP. AND AGAIN, I REALLY WANT TO  
6 THANK THE MEMBERS OF THE PUBLIC WHO TOOK THE TIME TO  
7 SEND US THEIR RESPONSE ORALLY OR IN WRITTEN FORM AND  
8 TELL THEM HOW VERY, VERY IMPORTANT THIS WAS TO US, AND  
9 AS YOU WILL SEE FROM OUR WORK TODAY, HOW SERIOUSLY WE  
10 TOOK IT AND HOW IT HAS AFFECTED SOME OF THE DECISIONS  
11 THAT WE'VE MADE.

12 AGAIN, I SAY TO YOU THAT THIS WILL ALWAYS BE  
13 A WORK IN PROGRESS. WE WILL CONTINUE TO MEET  
14 THROUGHOUT THE YEARS. AND AS THE SCIENCE CHANGES, SO  
15 WILL THE RULES. AND WITH THAT, I TURN IT OVER TO  
16 BERNIE LO.

17 CO-CHAIR LO: THANKS, SHERRY. I'M GOING TO  
18 ASK GEOFF LOMAX TO GIVE US A SUMMARY OF THE PROCESS OF  
19 PUBLIC COMMENTARY AND TO SORT OF ORIENT US TO THE VERY  
20 NICE SUMMARY THAT HE AND STAFF HAVE PREPARED.

21 MR. LOMAX: GREAT. THANK YOU, BERNIE. AS  
22 YOU ALL HAVE IN YOUR PACKET AND IT'S ALSO ON THE TABLE  
23 AVAILABLE TO THE PUBLIC IS A DOCUMENT THAT WILL  
24 HOPEFULLY LOOK FAMILIAR AT THIS POINT. IT IS TITLED  
25 "SUMMARY OF PUBLIC COMMENTS," AND IT'S THIS PARTICULAR

1 VERSION THAT SAYS RECEIVED ON OR AFTER THE 10TH OF  
2 FEBRUARY. IT'S A SPREADSHEET-TYPE DOCUMENT.

3 AT PREVIOUS MEETINGS YOU'VE RECEIVED ALL THE  
4 COMMENTS LEADING UP TO THIS. AND WE JUST THOUGHT,  
5 RATHER THAN INCLUDING A WHOLE REPEAT OF THAT, FOR THE  
6 PURPOSE OF SAVING PAPER, WE'VE INCLUDED THE COMMENTS  
7 RECEIVED AFTER THE 10TH OF FEBRUARY. SO YOU WILL SEE  
8 THE COMMENT NUMBERS ON THE LEFT-HAND COLUMN START 2-47.  
9 WE HAD 46 COMMENTS IN THE INITIAL PHASE WHEN WE  
10 DEVELOPED THE REGULATIONS TO SEND TO THE ICOC. SO THE  
11 TWO INDICATES SORT OF PART 2, IF YOU WILL, AND ALL  
12 DOCUMENTS RECEIVED DURING THE OFFICIAL OFFICE OF  
13 ADMINISTRATIVE LAW PUBLIC COMMENTING PERIOD ARE  
14 INDICATED WITH THAT 2.

15 SO THIS DOCUMENT, I WILL JUST IMPRESS UPON  
16 EVERYONE, IT'S STILL IN DRAFT PHASE. WE HAVEN'T QUITE  
17 GOTTEN EVERY COMMENT IN THE LEVEL OF DETAIL WE'D LIKE,  
18 IN PART BECAUSE OF THE TIGHT COUPLING BETWEEN THE  
19 CLOSING OF THE COMMENT PERIOD AND THIS MEETING. SO AS  
20 A RESULT, YOU WILL FIND A NUMBER OF ORIGINAL COMMENTS  
21 IN YOUR PACKET AS WELL. WE THOUGHT IT BEST SIMPLY TO  
22 INCLUDE THOSE FOR THE SAKE OF BEING CLEAR.

23 AND SO WE WILL BY THE END OF THIS PROCESS AND  
24 I HOPE BY THE END OF NEXT WEEK HAVE THIS DOCUMENT, THE  
25 FULL SUMMARY DONE AND TO INCORPORATE EVERYTHING WHICH

1 WE RECEIVED TO DATE.

2 ONE OTHER DOCUMENT I WOULD JUST LIKE TO DRAW  
3 TO YOUR ATTENTION, BECAUSE I THINK IT WILL BE  
4 INFORMATIVE IN TERMS OF THE DELIBERATIONS AND JUST TO  
5 REFRESH FOLKS' MEMORY, THERE'S A SECOND DOCUMENT CALLED  
6 "SUMMARY OF ORIGINAL BASIS FOR THE CIRM MES  
7 REGULATIONS." AGAIN, IT TAKES A SPREADSHEET FORMAT.  
8 AND WHAT THAT IS IS A BREAKDOWN OF THE ENTIRE  
9 REGULATIONS ON A SECTION-BY-SECTION BASIS, AND IT  
10 INCLUDES REFERENCE FOR THE UNDERLYING REASONING OR THE  
11 BASIS FOR THAT REGULATION. SO YOU WILL SEE IT  
12 REFERENCES QUITE FREQUENTLY THINGS LIKE THE NAS  
13 GUIDELINES, EXISTING CALIFORNIA REGULATIONS, AND IN  
14 ADDITION, IT REFERENCES TO THE SWG TRANSCRIPTS. SO  
15 THOSE TYPES OF NOTATIONS ARE INTENDED TO SORT OF REMIND  
16 FOLKS WHAT THE BASIS FOR ANY PARTICULAR ASPECT OF  
17 REGULATIONS WERE. AND AGAIN, YOU MIGHT FIND THAT  
18 HELPFUL FOR REFERENCE PURPOSES AS WE GO THROUGH SOME OF  
19 THE COMMENTS TODAY. AND THIS IS A DOCUMENT, AGAIN, WE  
20 CAN MAKE AVAILABLE IN ELECTRONIC FORMAT BECAUSE ALL THE  
21 REFERENCE MATERIALS ARE ACTUALLY ORIGINAL DOCUMENT.  
22 THESE DOCUMENTS ARE LIVE AND YOU CAN LINK DIRECTLY TO  
23 THEM.

24 I THINK WE HAVE ONE OTHER PERSON ON THE LINE.  
25 CO-CHAIR LO: DID SOMEONE JUST JOIN?



1 DR. KIESSLING: HOW MANY PEOPLE ARE ON  
2 SPEAKER PHONE?

3 DR. WAGNER: THIS IS JOHN WAGNER.

4 CO-CHAIR LO: JOHN, WELCOME. IT'S BERNIE LO.  
5 THANKS FOR JOINING US. WE ALSO HAVE ZACH HALL AND  
6 KEVIN EGGAN ON SPEAKER PHONE. IF ANY OF YOU AREN'T  
7 UNDERSTANDING WHAT WE'RE SAYING, JUST INTERRUPT AND  
8 WE'LL TRY AND SPEAK UP OR CLARIFY.

9 DR. HALL: WE CAN UNDERSTAND THE PEOPLE ON  
10 THE SPEAKER PHONE VERY WELL. WE HAVE GREAT DIFFICULTY  
11 WITH THE ON-SITE SPEAKERS. SHERRY CAME THROUGH  
12 REASONABLY, EITHER BERNIE OR GEOFF WERE UNINTELLIGIBLE.

13 MR. LOMAX: HOW'S THIS? SO THAT BRINGS US UP  
14 TO --

15 (INTERRUPTION IN PROCEEDINGS.)

16 CO-CHAIR LO: JOHN AND ZACH AND KEVIN, IS  
17 THIS ANY BETTER AFTER MOVING THE SPEAKER PHONE? ZACH,  
18 JOHN, CAN YOU HEAR US ANY BETTER? WE MOVED THE PHONE.  
19 DOES THIS HELP?

20 DR. HALL: WHEN YOU JUST ASKED, I UNDERSTOOD  
21 THE QUESTION, SO I GUESS IT IS marginally BETTER.

22 CO-CHAIR LO: AGAIN, KEEP US APPRISED IF YOU  
23 ARE NOT HEARING US.

24 DR. HALL: THAT ACTUALLY WAS FINE. LET'S  
25 CARRY ON AS IS.

1 MR. LOMAX: THANK YOU. THEN FINALLY --

2 DR. HALL: THANK YOU FOR REARRANGING.

3 MR. LOMAX: WHAT I'D LIKE TO DO IS TURN TO  
4 SCOTT TOCHER JUST TO GIVE A QUICK DESCRIPTION OF THE  
5 PROCESS FROM HERE ON OUT AS IT PERTAINS TO THE OFFICE  
6 OF ADMINISTRATIVE LAW PROCEDURES.

7 MR. TOCHER: ALL RIGHT. I'LL TRY AND MAKE IT  
8 FAST. BASICALLY FROM THIS POINT FORWARD, THE WORKING  
9 GROUP WILL CONSIDER THE -- AFTER CONSIDERING THE PUBLIC  
10 COMMENT FROM TODAY, ANY REVISIONS TO THE REGULATIONS  
11 WILL BE POSTED ON THE CIRM WEBSITE FOR AN ADDITIONAL  
12 15-DAY COMMENT PERIOD. THE TOTALITY OF THE COMMENTS  
13 AND REVISIONS TO THE REGULATIONS WILL BE THEN PRESENTED  
14 IN JUNE AT THE NEXT ICOC MEETING FOR FINAL APPROVAL BY  
15 THE ICOC.

16 WITH THAT FINAL APPROVAL, THE REGULATIONS  
17 WILL BE SUBMITTED, ALONG WITH THE FINAL STATEMENT OF  
18 REASONS, WHICH ADDRESS ALL THE PUBLIC COMMENTS, TO THE  
19 OFFICE OF ADMINISTRATIVE LAW, WHICH WILL THEN HAVE 30  
20 BUSINESS DAYS TO REVIEW THE REGULATIONS AND THE  
21 STATEMENT OF REASONS AND THE OTHER SUPPORTING  
22 DOCUMENTATION. AND UPON THAT REVIEW, WILL EITHER  
23 APPROVE AND PUBLISH THE REGULATIONS, AND THEY WILL BE  
24 IN FULL FORCE AND EFFECT, OR MAY IN SOME CIRCUMSTANCES  
25 COMMUNICATE WITH CIRM FOR ADJUSTMENTS OR REVISIONS TO

1 THE REGULATIONS AS THEY REQUIRE.

2 CO-CHAIR LO: THANKS, SCOTT. ANY QUESTIONS  
3 ABOUT THE PROCEDURES? OKAY.

4 IF SOMEONE CAN FLIP ON THE SLIDES. WE  
5 RECEIVED A LOT COMMENTS. WE WERE VERY, VERY GRATEFUL  
6 TO THE PUBLIC FOR THEIR THOUGHTFUL COMMENTS, AND ALSO  
7 IN A NUMBER OF CASES THEY SORT OF PROVIDED ADDITIONAL  
8 INFORMATION TO EXPLAIN THEIR POINTS. WE TRIED TO SORT  
9 THESE INTO SEVERAL DIFFERENT CATEGORIES. WE OBVIOUSLY  
10 CAN'T TALK ABOUT EVERYTHING TODAY, AND WE DON'T WANT TO  
11 OPEN UP ISSUES THAT WE ALREADY DISCUSSED AT LENGTH.

12 THERE ARE SOME SUGGESTIONS WHICH WE THINK ARE  
13 TECHNICAL SUGGESTIONS WHERE A COUPLE OF WORDS NEED TO  
14 BE CHANGED WHERE THERE'S NO DISAGREEMENT ON THE  
15 INTENTION OF THE REGULATIONS, BUT THE WORDING WASN'T  
16 QUITE RIGHT. AND WE'RE PROPOSING NOT TO GO INTO ALL  
17 THOSE.

18 THERE WERE ALSO A NUMBER OF COMMENTS FROM  
19 PEOPLE -- NOT EVERYONE AGREES WITH US, AND I THINK IT'S  
20 VERY HEALTHY FOR PEOPLE TO EXPRESS THEIR OPINIONS. BUT  
21 WHERE THEY MERELY REGISTER DISAGREEMENT ON A TOPIC WE  
22 HAD DISCUSSED AND LISTENED TO THEIR COMMENTS AND  
23 DELIBERATED, I DON'T THINK WE WANT TO OPEN ALL THAT UP  
24 TODAY. THERE ARE A NUMBER OF ISSUES WHERE I THINK  
25 THERE'S ENOUGH NEW THINKING, NEW SUGGESTIONS, THAT IT

1 WOULD BE VERY WISE TO REVISIT SOME TOPICS THAT WE HAD  
2 COVERED IN THE REGULATIONS AND MAY WELL WANT TO CHANGE  
3 THE REGULATIONS ON SOME OF THOSE.

4 IN ADDITION, THERE WERE SOME OTHER TOPICS  
5 THAT WE REALLY HAD NOT CONSIDERED IN DEPTH AT THE TIME  
6 OF ISSUING OUR RECOMMENDATIONS TO THE ICOC IN FEBRUARY.  
7 I THINK IT'S VERY IMPORTANT THAT WE BEGIN TO GRAPPLE  
8 WITH, TO ADDRESS THESE VERY IMPORTANT COMMENTS. AND I  
9 THINK THAT'S SOMETHING ELSE I'D LIKE TO DO TODAY.

10 JUST FOR THE SAKE OF TRYING TO GIVE US A  
11 SENSE OF WHERE I HOPE WE CAN GO TODAY, I MADE A COUPLE  
12 OF SLIDES TO SORT OF SELECT OUT THE ISSUES THAT I THINK  
13 WE REALLY WANT TO HAVE A DISCUSSION ON AND TRY AND  
14 REACH SOME RESOLUTION ON.

15 THE FIRST SLIDE, AND I'LL READ THEM OUT FOR  
16 THE FOLKS ON THE PHONE OR MAYBE WE CAN E-MAIL THESE TO  
17 THE FOLKS ON THE PHONE. IS THAT POSSIBLE?

18 FIRST SLIDE IS ISSUES THAT NEED DISCUSSION  
19 AND, I THINK, RESOLUTION. WE GOT COMMENTS BACK ON  
20 OOCYTE DONATION. AND THE TWO SPECIFIC COMMENTS ARE THE  
21 WORDING OF THEIR LANGUAGE REGARDING COMPROMISE TO THE  
22 WOMAN'S REPRODUCTIVE SUCCESS. IT THINK THERE'S SOME  
23 VERY HELPFUL LANGUAGE THERE THAT WE WANT TO LOOK AT AND  
24 POSSIBLY ADOPT.

25 THERE ALSO WERE A LOT OF COMMENTS ABOUT THE

1 DELIBERATION PERIOD BEFORE THE OOCYTE DONOR GIVES FINAL  
2 CONSENT AND, AGAIN, SOME THOUGHTFUL COMMENTS THAT  
3 RAISED IDEAS WE DID NOT REALLY CONSIDER IN OUR PREVIOUS  
4 DELIBERATIONS.

5 SECOND BIG ISSUE IS DONATION OF FETAL TISSUE  
6 AND CORD BLOOD FOR CIRM-FUNDED RESEARCH AND THE CONSENT  
7 PROCESS FROM THE MALE PROGENITOR. AGAIN, THESE ARE  
8 DIFFICULT, IMPORTANT ISSUES, AND I THINK THERE ARE  
9 POINTS MADE THAT WE WANT TO TAKE INTO ACCOUNT.

10 AND THE THIRD OF THOSE ISSUES HAS TO DO WITH  
11 WHETHER CIRM SHOULD FUND RESEARCH THAT YIELDS  
12 INHERITABLE GENETIC MODIFICATION IN HUMANS. IN OTHER  
13 WORDS, IF RESEARCH TRANSPLANTS A GENETICALLY MODIFIED  
14 CELL INTO A HUMAN EMBRYO, IS THAT SOMETHING CIRM IS  
15 WILLING TO FUND? AND ALSO IS GENETIC MANIPULATION OF A  
16 EMBRYO OPEN FOR CIRM FUNDING? I THINK THERE'S SOME  
17 ISSUES THERE THAT WE DIDN'T CONSIDER THAT REALLY HAVE  
18 TO DO WITH SEPARATING THE REPRODUCTION OF HUMANS THAT  
19 HAVE GENETIC MODIFICATIONS THAT WOULD PASS ON IN THE  
20 GERM LINE VERSUS, FOR EXAMPLE, SCIENTIFIC STUDIES WHERE  
21 THERE WILL BE NO SUBSEQUENT BREEDING.

22 SO THOSE WERE THREE ISSUES, I THINK, IT WOULD  
23 BEHOOVE US TO THINK ABOUT THE SUGGESTIONS THAT WERE  
24 MADE.

25 NEXT SLIDE, THERE ARE TWO OTHER ISSUES WHICH

1 ARE IMPORTANT, I DON'T THINK AS COMPLICATED, BUT ARE  
2 CLEARLY VERY IMPORTANT. ONE IS THE DEFINITION OF  
3 COVERED STEM CELL LINES. WE HAD A NUMBER OF COMMENTS,  
4 PARTICULARLY FROM RESEARCHERS AND RESEARCH  
5 INSTITUTIONS, THAT THE DEFINITION WE MADE IN FEBRUARY  
6 WAS TOO BROAD AND SWEEPED IN ADULT STEM CELL LINES THAT  
7 REALLY DIDN'T REQUIRE THE DEGREE OF OVERSIGHT THAT  
8 SEEMED TO BE IMPLIED IN OUR WORDING.

9 AND A SECOND ISSUE IS CARE FOR THE  
10 COMPLICATIONS OF OOCYTE DONATION IN WOMEN WHO ARE IN  
11 CIRM-FUNDED RESEARCH PROJECTS. AND AGAIN, NO QUESTION  
12 ABOUT -- THE IDEA WE PUT FORWARD, I THINK, WAS VERY  
13 WELL RECEIVED, BUT SOME SUGGESTIONS AS TO HOW TO  
14 REFRAME OUR LANGUAGE TO GIVE A LITTLE MORE FLEXIBILITY  
15 FOR HOW THAT CARE IS PAID FOR.

16 SO THOSE TWO ISSUES I THINK WE DO NEED TO  
17 RESOLVE, BUT HOPE WILL NOT REQUIRE AS DETAILED  
18 DISCUSSION.

19 THEN I THINK THERE ARE TWO ISSUES WHICH I  
20 WOULD SAY THEY'RE NOT NEW ISSUES, BUT THEY'RE COMMENTS  
21 WE RECEIVED, VERY EXTENSIVE COMMENTS, THAT GO INTO THE  
22 ISSUES OF RECORDKEEPING AND ASSURANCE OF COMPLIANCE IN  
23 MORE DEPTH THAN WE WERE ABLE TO DO IN THE FEBRUARY  
24 VERSION. AND I THINK GIVEN THE IMPORTANCE OF  
25 ACCOUNTABILITY AND TRANSPARENCY, WE NEED TO REALLY

1 SPEND SOME TIME THINKING ABOUT THESE ISSUES AND  
2 THINKING ABOUT THE IDEAS THAT WERE RAISED IN THE PUBLIC  
3 COMMENTS.

4 AGAIN, AS SHERRY ALWAYS SO WISELY REMINDS US,  
5 THESE ARE ISSUES THAT WE DO NOT NEED TO RESOLVE TODAY.  
6 WE PROBABLY CAN'T RESOLVE THEM TODAY, BUT THEY'RE  
7 ISSUES THAT WE NEED TO KIND OF MAKE PART OF OUR  
8 BUSINESS AND CIRM BUSINESS. AND THIS WILL BE AN  
9 ONGOING PROCESS, BUT I THINK IT'S GOOD TO START THAT.

10 SO ASSUMING THAT THERE ARE NO OBJECTIONS TO  
11 SORT OF THIS PROPOSED MORE DETAILED AGENDA, WHAT I  
12 WOULD SUGGEST IS THAT WE NOW TURN TO THE ISSUES ONE BY  
13 ONE AND TRY AND WORK THROUGH THEM.

14 OKAY. AS WE DO THAT, I COMMEND TO YOU THIS  
15 DOCUMENT THAT GEOFF PUT TOGETHER CALLED "SUMMARY OF  
16 MAJOR COMMENTS AND RECOMMENDATIONS ON THE CIRM MES  
17 REGULATIONS." THE FRONT PAGE LOOKS LIKE THIS. IT'S  
18 THE THICKEST DOCUMENT IN YOUR BOOK. AND WHAT THIS  
19 GIVES, WHAT GEOFF HAS VERY NICELY DONE IS CULLED OUT  
20 THE STATEMENT FROM THE PUBLIC IN THE COMMENTS, THE  
21 ORIGINAL LANGUAGE OF OUR RECOMMENDATIONS IN FEBRUARY,  
22 AND THEN PROPOSED OR POSSIBLE LANGUAGE.

23 WE HAVE USED THE NOTATIONS A, B, AND C TO  
24 DESIGNATE A ARE THE ONES THAT WE REALLY WANT TO TRY AND  
25 DISCUSS BECAUSE WE MAY WANT TO CHANGE WHAT WE

1 RECOMMENDED TO THE ICOC. C ARE THE TECHNICAL COMMENTS.  
2 AND B ARE REALLY RELATIVELY STRAIGHTFORWARD CHANGES OR  
3 COMMENTS THAT WE'VE ALREADY ADDRESSED AND CHOSEN NOT TO  
4 AGREE WITH.

5 BUT I WANT TO START WITH THE REPRODUCTIVE  
6 SUCCESS. AND GEOFF, I'M GOING TO HAVE TO ASK YOU TO  
7 HELP ME HERE WITH WHICH NUMBER THAT IS.

8 MR. LOMAX: I BELIEVE IT IS -- BEAR WITH ME.  
9 SORRY -- COMMENT NO. 7. IF YOU NOTICE, THEY'RE ALL --  
10 THERE'S AN ORDERING OF NUMBER ON THE UPPER LEFT-HAND  
11 CORNER. IT'S THE FIRST PART.

12 CO-CHAIR LO: SO THIS IS ON PAGE 6 OF YOU'RE  
13 FOLLOWING THE PAGES, AND AT THE VERY TOP, THAT UPPER  
14 LEFT-HAND BOX WHERE THE POUND IS THAT SAYS THE NO. 7.

15 AND LET ME JUST READ IT TO MAKE SURE WE'RE  
16 ALL ORIENTED. THE COMMENT FROM THE PUBLIC IS THE  
17 MEANING OF "SHALL NOT COMPROMISE THE OPTIMAL  
18 REPRODUCTIVE SUCCESS" -- THIS IS OF THE WOMAN DONATING  
19 OOCYTES FOR RESEARCH -- "NEEDS TO BE CLARIFIED."  
20 FIRST, THE STATEMENT MAY BE INTERPRETED TO MEAN THE  
21 RESEARCHER MUST NOT ENGAGE IN ANY ACTIVITY THAT POSES A  
22 HEALTH RISK. IF THIS IS THE CASE, THEN OOCYTE  
23 RETRIEVAL WOULD NOT BE ALLOWED BECAUSE IT IS  
24 CONCEIVABLE THAT HER FERTILITY MAY BE IMPACTED.

25 AT A MINIMUM THE SUGGESTION FROM THE PUBLIC



1 COMMENTER IS THE LANGUAGE SHOULD BE CHANGED TO STATE  
2 "SHALL NOT KNOWINGLY COMPROMISE." IT APPEARS THAT THE  
3 INTENT OF THE WORKING GROUP IS THAT OOCYTES NOT BE  
4 COMMITTED OR DIVERTED TO RESEARCH UNTIL THE WOMAN'S  
5 FERTILITY GOALS OR TREATMENT IS COMPLETE. THE LANGUAGE  
6 NEEDS TO STATE IN A CLEAR MANNER THAT OOCYTES INTENDED  
7 FOR REPRODUCTIVE PURPOSES ARE USED FOR SUCH PURPOSES  
8 AND NOT USED FOR RESEARCH UNLESS THE FERTILITY  
9 TREATMENT IS COMPLETE.

10 AGAIN, THESE ARE IMPORTANT COMMENTS BECAUSE  
11 WE WANT TO REALLY PROTECT THE WOMEN WHO ARE UNDERGOING  
12 INFERTILITY TREATMENT, BUT ALSO INTERESTED IN STEM CELL  
13 RESEARCH TO MAKE SURE THAT THEY MAKE A TRULY INFORMED  
14 DECISION. SO THAT AT THE BOTTOM RIGHT-HAND BOX IS  
15 PROPOSED OR POSSIBLE LANGUAGE. AND AGAIN, LET ME JUST  
16 READ THROUGH IT.

17 NO. 1, FOR A WOMAN -- AND THE UNDERLINING,  
18 CORRECT ME, GEOFF, IS THE ALTERED LANGUAGE. IS THAT  
19 CORRECT?

20 MR. LOMAX: THAT'S CORRECT. IN GENERAL, THE  
21 IDEA IN THIS DOCUMENT IS THAT WHEN YOU SEE DOUBLE  
22 UNDERLINING, IT'S NEW LANGUAGE ADDED TO THE ORIGINAL  
23 LANGUAGE. AND I BELIEVE THAT'S CONSISTENT THROUGHOUT  
24 THE DOCUMENT, BUT THERE MAY BE SOME MINOR VARIANCE TO  
25 THAT.

1 CO-CHAIR LO: SO WHAT WE PROPOSE FIRST IS TO  
2 INSERT THE WORD "KNOWINGLY" INTO THE ORIGINAL LANGUAGE,  
3 BUT TO SAY, "FOR A WOMAN PROVIDING OOCYTES FOR RESEARCH  
4 AND CLINICAL INFERTILITY TREATMENT, EITHER FOR HERSELF  
5 OR ANOTHER WOMAN, THE DISPOSITION OF SUCH OOCYTES SHALL  
6 NOT KNOWINGLY COMPROMISE THE OPTIMAL REPRODUCTIVE  
7 SUCCESS OF THE WOMAN IN INFERTILITY TREATMENT. SO THAT  
8 IT'S REALLY PUTTING IT -- I THINK MAKING SURE THE WOMAN  
9 MAKES AN INFORMED DECISION.

10 WE GO ON TO SAY, SUBPART A, A WOMAN  
11 UNDERGOING STIMULATION TO PRODUCE OOCYTES FOR HER OWN  
12 REPRODUCTIVE USES MAY NOT DONATE ANY EGGS TO RESEARCH  
13 UNLESS SHE HAS DETERMINED THAT SHE DOES NOT WANT OR  
14 NEED THEM TO OPTIMIZE HER OWN CHANCES FOR REPRODUCTIVE  
15 SUCCESS.

16 AND B, A WOMAN UNDERGOING STIMULATION TO  
17 PRODUCE OOCYTES FOR DONATION TO ANOTHER PERSON'S  
18 REPRODUCTIVE EFFORT. SO THAT'S THE OOCYTE DONOR IN AN  
19 INFERTILITY PROGRAM MAY NOT DONATE ANY OF THESE EGGS TO  
20 RESEARCH UNLESS, (A), THE DONATION IS EXPRESSLY  
21 PERMITTED BY THE RECIPIENT WHO IS RECEIVING HER OOCYTES  
22 FOR REPRODUCTION; AND, (B) HER DONATION OF OOCYTES FOR  
23 RESEARCH IS DONE WITHOUT VALUABLE CONSIDERATION. AND  
24 WE WOULD CROSS REFERENCE THE DEFINITION OF VALUABLE  
25 CONSIDERATION. SO THE NOTION IS SHE WOULDN'T BE PAID

1 EXTRA FOR DONATING TO RESEARCH.

2 SO LET'S HEAR WHAT YOUR THOUGHTS ARE IN THESE  
3 PROPOSED CHANGES TO OUR LANGUAGE IN RESPONSE TO THIS  
4 COMMENT. THOUGHTS? SUGGESTIONS?

5 CO-CHAIR LANSING: I THINK IT'S GOOD BECAUSE  
6 I THINK THIS WAS ORIGINALLY OUR INITIAL INTENT. ONCE  
7 AGAIN, IF IT'S NOT COMING ACROSS TO THE PUBLIC, AND I'M  
8 GLAD THAT THEY'VE DRAWN THIS TO OUR ATTENTION, I THINK  
9 THIS REALLY CLARIFIES IT. SO I THINK THIS WAS OUR  
10 INTENT. IT'S JUST THAT SOMETIMES WHAT WE THINK IS  
11 CLEAR, THE LANGUAGE ISN'T AS CLEAR AS WE WOULD LIKE IT,  
12 SO I PERSONALLY AM VERY COMFORTABLE WITH THIS.

13 DR. OLDEN: I AM TOO. I AGREE. I READ THE  
14 PUBLIC COMMENT, AND I THOUGHT IT WAS APPROPRIATE. AND  
15 I THINK THE RESPONSE IS JUST FINE.

16 CO-CHAIR LO: SEVERAL OF YOU HAVE ACTUALLY  
17 BEEN INVOLVED WITH OOCYTE DONATION CLINICALLY, ROB, OR  
18 FOR RESEARCH, ANN. DOES THIS SEEM ON TARGET FROM YOUR  
19 POINTS OF VIEW?

20 DR. KIESSLING: ARE WE TALKING ABOUT  
21 ACCEPTING NO. 1? ARE WE TALKING ABOUT SIMPLY ACCEPTING  
22 VERSION NO. 1?

23 CO-CHAIR LO: I THINK 1(A) AND (B) WERE THE  
24 SUGGESTIONS FROM STAFF, THAT WE INCLUDE ALL THE  
25 LANGUAGE IN THAT RIGHT-HAND BOX.

1 DR. KIESSLING: WE'RE GOING TO KEEP ALL THREE  
2 OF THESE?

3 CO-CHAIR LO: YEAH. 1(A) AND (B). (A) AND  
4 (B) WOULD BE SUBPARTS.

5 ONE QUESTION I WANT TO ASK THE SCIENTISTS.  
6 THIS PARTICULARLY NOW SPECIFIES HORMONAL STIMULATION.  
7 I THINK THAT'S MEANT STIMULATION. DO WE MEAN THIS TO  
8 APPLY ALSO TO OTHER MODES OF OOCYTE RETRIEVAL IF THOSE  
9 BECOME FEASIBLE? OBVIOUSLY THE HORMONAL STIMULATION  
10 RAISES MORE QUESTIONS ABOUT ADVERSE EVENTS; BUT IN  
11 TERMS OF REPRODUCTIVE SUCCESS, I'M JUST WONDERING IS  
12 LIKE RETRIEVAL OF IMMATURE OOCYTES, IF THAT BECOMES  
13 REALISTIC, OR FREEZING, YOU KNOW, TAKING A BIOPSY. IS  
14 THAT -- DO THEY ALSO NEED TO SORT OF TAKE INTO ACCOUNT  
15 THE OPTIMIZATION OF THEIR REPRODUCTIVE SUCCESS?

16 DR. TAYLOR: THIS IS ROB TAYLOR. IT'S AN  
17 INTERESTING QUESTION THAT I DON'T THINK WE REALLY KNOW  
18 HOW TO PREDICT THE RISKS OF MULTIPLE OR ATTEMPTED  
19 REMOVAL OF MULTIPLE IMMATURE OOCYTES FROM AN  
20 UNSTIMULATED SUBJECT. IT'S NOT SOMETHING WE'VE  
21 ACTUALLY DONE CLINICALLY OR PRACTICABLY. AND I WOULD  
22 SUBMIT THAT THERE MAY BE MORE RISKS TO THE DONOR THAN  
23 IN CONTROLLED OVARIAN HYPERSTIMULATION AND OOCYTE  
24 RECOVERY THE WAY WE'RE DOING IT CURRENTLY.

25 SO WHAT I LIKE, AND I THINK THIS IS VERY,

1 VERY WELL WRITTEN, WHAT I LIKE ABOUT IT IS THAT IT  
2 ACTUALLY SORT OF FOCUSES THE RISKS OF THIS PROCEDURE ON  
3 THE REPRODUCTIVE OUTCOMES BECAUSE THERE ARE OTHER  
4 RISKS, RISKS OF ANESTHESIA, THAT ARE SOMEWHAT UNRELATED  
5 TO REPRODUCTIVE OUTCOME. AGAIN, I WOULD SAY THAT THE  
6 DATA THAT I'M FAMILIAR WITH AND ONE OF THE PROBABLY  
7 BETTER PAPERS THAT I'VE SEEN IN THE LAST COUPLE OF  
8 YEARS IS FROM MADRID IN SPAIN FROM JUAN GARCIA VELASCO,  
9 I THINK, IS THE NAME. AND IT WAS REALLY LOOKING AT  
10 SUBSEQUENT CYCLES IN WOMEN WHO HAVE UNDERGONE IVF  
11 OOCYTE RETRIEVAL.

12 THE CONCERN HAS BEEN ARE WE ACTUALLY REDUCING  
13 THE NUMBER OF EGGS THESE WOMEN WILL EVER HAVE AND  
14 COMPROMISE THEIR LONG-TERM FERTILITY? AND THEN THE  
15 DATA REALLY SUGGESTS, AS WE'VE UNDERSTOOD IT, THAT  
16 OVARIAN STIMULATION WITH GONADOTROPINS RECRUITS A  
17 COHORT THAT IS TYPICALLY 30 OR SOME IN A CYCLE THAT  
18 WILL BE DESTINED TO ATRESIA ANYWAY. AND THAT WE'RE  
19 REALLY NOT RECRUITING FROM A POOL OF CELLS THAT  
20 ULTIMATELY GIVE RISE TO THE SORT OF LONG-TERM  
21 REPRODUCTIVE HEALTH.

22 SO YOU'RE MAINTAINING OOCYTES THAT WOULD  
23 OTHERWISE UNDERGO ATRESIA. AND WHEN THEY'VE LOOKED AT  
24 AGE-MATCHED STIMULATION SORT OF SUCCESS IN WOMEN WHO  
25 PREVIOUSLY HAD IVF CYCLES VERSUS THOSE THAT HADN'T, THE

1 RESULTS WERE VERY, VERY SIMILAR. SO AS YOU GET OLDER,  
2 THE NUMBER OF EGGS THAT WE RECOVER IS DECREASED, BUT IT  
3 DOESN'T SEEM TO BE AN EFFECT OF HAVING UNDERGONE A  
4 PREVIOUS IVF.

5 CO-CHAIR LO: IT'S THE AGE, NOT THE HORMONAL.  
6 SO IT SOUNDS LIKE, IF I CAN EXTEND WHAT YOU'RE SAYING,  
7 THAT UNTIL FURTHER EVIDENCE COMES FORTH, FOR EXAMPLE,  
8 FROM THE SYMPOSIUM THAT CIRM IS SPONSORING WITH THE  
9 NAS, THAT WE SHOULD NOT EXTEND THE LANGUAGE BEYOND WHAT  
10 WE KNOW SCIENTIFICALLY IS A CONCERN, BUT OBVIOUSLY  
11 WE'LL LEAVE OURSELVES OPEN TO MODIFYING THIS IF NEED BE  
12 AT A LATER DATE IF THE EVIDENCE WARRANTS.

13 DR. PRIETO: IT SEEMS TO ME THE PART OF YOUR  
14 QUESTION WAS IS THE WORD "STIMULATION" SUFFICIENTLY  
15 BROAD IN GENERAL TO COVER ANY TECHNIQUES THAT MIGHT  
16 EXIST IN THE FUTURE FOR RETRIEVAL OF OOCYTES?

17 CO-CHAIR LO: AGAIN, I'M NOT --

18 DR. PRIETO: I DON'T KNOW IF IT IS. I DON'T  
19 KNOW IF THERE'S SOME OTHER WORDING.

20 CO-CHAIR LO: I'M NOT A REPRODUCTIVE  
21 BIOLOGIST.

22 DR. PRIETO: I THINK IT WOULD HAVE TO BE  
23 PRETTY GENERAL TO ENCOMPASS ANYTHING FORESEEABLE OR NOT  
24 YET FORESEEABLE.

25 DR. TAYLOR: I GUESS I WOULD SUGGEST THAT IF

1 WE GOT REALLY, REALLY EXTRAORDINARILY GOOD CLINICALLY  
2 AT DOING THIS, IT MAY WELL BE POSSIBLE TO TAKE NATURAL  
3 OVULATION, RETRIEVE A NATURALLY MATURE EGG, AND HAVE A  
4 VERY HIGH RATE OF PREGNANCY SUCCESS. IF THAT WERE TO  
5 BE THE CASE, THEN IT WOULD REALLY LIMIT THE NEED TO DO  
6 OVARIAN HYPERSTIMULATION, CONTROLLED OVARIAN  
7 HYPERSTIMULATION, AND MIGHT, IN FACT, SORT OF LIMIT THE  
8 NUMBER OF EXTRA EMBRYOS THAT WOULD BE AVAILABLE FOR  
9 THIS TYPE OF WORK, UNLESS THROUGH A DONOR TYPE OF A  
10 PROCESS.

11 BUT, AGAIN, I GUESS I THINK STIMULATION IS  
12 PROBABLY A REASONABLE WAY. WE CHANGED A LOT OF  
13 PROTOCOLS. WE'RE USING GNH ANTAGONISTS NOW RATHER THAN  
14 AGONISTS. I THINK STIMULATION IS PROBABLY GOOD  
15 LANGUAGE TO MAINTAIN IN THERE AT LEAST FOR THE  
16 FORESEEABLE FUTURE.

17 CO-CHAIR LO: GOOD. ALTA.

18 MS. CHARO: GEOFF WAS SITTING NEXT TO ME AND  
19 WAS JUST WONDERING ALONG WITH ME ABOUT WHETHER OR NOT  
20 THE LANGUAGE, THE ORIGINAL LANGUAGE, WHICH TALKED ABOUT  
21 PROVIDING OOCYTES, AS OPPOSED TO UNDERGOING  
22 STIMULATION, MIGHT BE PREFERABLE BECAUSE IT DOESN'T  
23 PRESUPPOSE A PARTICULAR MEDICAL TECHNIQUE OF ANY SORT  
24 NOW OR IN THE FUTURE. SO THAT UNDER THE PROPOSED OR  
25 POSSIBLE LANGUAGE HEADING, WE WOULD HAVE, NO. 1, FOR A

1 WOMAN PROVIDING OOCYTES, AS IT NOW READS. AND THEN  
2 UNDER (A), A WOMAN PROVIDING OOCYTES FOR HER OWN  
3 REPRODUCTIVE USES, BLAH, BLAH, BLAH. AND THEN UNDER  
4 (B), A WOMAN PROVIDING OOCYTES FOR DONATION TO ANOTHER  
5 PERSON'S REPRODUCTIVE EFFORTS, BLAH, BLAH, BLAH.

6 CO-CHAIR LO: THAT'S MORE GENERAL AND WOULD  
7 COVER.

8 DR. TAYLOR: I AGREE ACTUALLY.

9 CO-CHAIR LO: OKAY. GOOD.

10 DR. KIESSLING: I HAVE A QUESTION ABOUT (A).  
11 I DON'T SEE HOW THIS IS GOING TO BE IMPLEMENTED. I  
12 DON'T SEE HOW YOU CAN ACCOMPLISH THIS.

13 DR. TAYLOR: I GUESS I'D GIVE A SUGGESTION  
14 FOR (A). SO IN A CASE WHERE A COUPLE HAD REPEATED  
15 UNSUCCESSFUL IVF CYCLES, YET THEY WANTED TO DONATE  
16 EXCESS OOCYTES OR EMBRYOS FOR RESEARCH, I WOULD THINK  
17 THAT IT WOULD -- CARETAKERS CERTAINLY INVOLVED WOULD  
18 WANT TO MAKE SURE THAT THAT INDIVIDUAL'S REPRODUCTIVE  
19 SUCCESS WAS OPTIMIZED POSSIBLY IN A DIFFERENT NUMERICAL  
20 WAY THAN SOMEBODY WHO HAD LOTS OF AVAILABLE EGGS AND  
21 EMBRYOS WHO HAD PREVIOUSLY HAD A SUCCESSFUL IVF CYCLE  
22 WHERE WE THOUGHT THE LIKELIHOOD OF SUCCESS --

23 DR. KIESSLING: BUT WHAT I'M CONCERNED ABOUT  
24 IS HOW IS THIS CONSENT FORM GOING TO READ? HOW IS THE  
25 WOMAN GOING TO CONSENT TO THIS? YOU CERTAINLY DON'T



1 WANT HER TO CONSENT TO IT THE DAY THE EGGS ARE  
2 COLLECTED. SHE'S GOT TO CONSENT TO THIS PRIOR.

3 MS. CHARO: YOU KNOW, I THINK HERE THE NOTION  
4 WAS THAT THERE IS POSSIBLY OUT THERE SOME SMALL  
5 POPULATION OF WOMEN WHO ARE ALREADY DOING SOMETHING  
6 LIKE THIS. FOR EXAMPLE, WOMEN WHO ARE UNDERGOING IVF,  
7 PRODUCING OOCYTES, BUT ALREADY KNOW THAT THEY DO NOT  
8 WANT TO HAVE FROZEN EMBRYOS LEFT OVER UNDER ANY  
9 CIRCUMSTANCES, AND SO ARE HAVING CONVERSATIONS WITH  
10 THEIR PHYSICIANS ABOUT NOT TRYING TO FERTILIZE ALL THE  
11 EGGS THAT THEY HAPPEN TO PRODUCE, BUT ONLY TRYING TO  
12 FERTILIZE SOME SMALLER NUMBER BECAUSE OF THEIR OWN  
13 CONCERNS ABOUT FROZEN EMBRYOS OR WHATEVER.

14 I DON'T KNOW IN PARTICULAR HOW EXACTLY THAT  
15 IS DONE EXCEPT THAT I PRESUME IT'S DONE BY SOME KIND OF  
16 CONVERSATION AT A RELEASE. I DON'T KNOW IF YOU ARE  
17 IMAGINING THAT WE NEED TO THEN BEGIN TO DELVE INTO  
18 ANOTHER WHOLE LEVEL OF REGULATIONS AS TO HOW THAT  
19 RELEASE IS DRAFTED. BUT THERE'S A POINT AT WHICH IT  
20 BECOMES UNREALISTIC AS A MATTER OF REGULATORY LANGUAGE  
21 AS OPPOSED TO PRACTICED, IMPLEMENTED REGULATION.

22 CO-CHAIR LO: LEAVE THAT UP TO THE IRB AND  
23 SCRO.

24 MS. CHARO: I'M SORRY THAT I CUT YOU OFF  
25 SHERRY RIGHT THERE.

1 CO-CHAIR LANSING: NO. NO. I CUT YOU OFF  
2 ACTUALLY. I THINK A LOT OF THESE ISSUES, BECAUSE  
3 THERE'S SEVERAL MORE THAT WE'RE GOING TO GO THROUGH,  
4 AND I'M GOING TO KEEP POPPING UP, I GUESS, WITH THIS,  
5 IS WE HAVE TO ASSUME THAT WHEN WE GIVE WOMEN ALL THIS  
6 INFORMATION, THAT IT'S THEIR CHOICE AS TO WHAT THEY  
7 WANT TO DO. WE'RE GIVING THEM A LOT OF INFORMED  
8 CONSENT, AND AT SOME POINT I RESPECT THE INTELLIGENCE  
9 OF EACH INDIVIDUAL WOMAN TO MAKE THESE DECISIONS.  
10 BECAUSE I MEAN WE'RE TAKING NO. 1, AND WE'RE EVEN  
11 INCREASING IT MORE AND MORE, AND GIVING THE WOMAN MORE  
12 INFORMATION TO THINK ABOUT IT. AND WE'RE GOING TO COME  
13 BACK TO IT FOR HOW LONG THEY SHOULD THINK AND ALL THE  
14 ISSUES THAT WE'RE TALKING ABOUT. BUT I RESPECT THE  
15 INDIVIDUAL WOMAN'S RIGHT TO MAKE THAT CHOICE.

16 DR. PRIETO: THIS IS ALL PART OF THE CONSENT  
17 PROCESS, AND WE JUST HAVE TO ASSUME THAT ONCE THAT  
18 PROCESS HAS BEEN GONE THROUGH AND A DECISION IS MADE,  
19 THAT THAT WOMAN IS MAKING HER BEST JUDGMENT OF WHAT'S  
20 IN HER INTEREST AND WHAT'S IN THE LARGER INTEREST THAT  
21 SHE WANTS TO SERVE.

22 CO-CHAIR LO: ANY COMMENTS, QUESTIONS FROM  
23 THOSE ON THE PHONE? ANY COMMENTS FROM THE MEMBERS OF  
24 THE PUBLIC HERE TODAY? PLEASE COME UP TO THE MIC AND  
25 INTRODUCE YOURSELF.

1 MS. GREENFIELD: I WOULD AGREE WITH A LOT OF  
2 THE COMMENT. DEBORAH GREENFIELD FROM THE PRO-CHOICE  
3 ALLIANCE FOR RESPONSIBLE RESEARCH. I WOULD AGREE WITH  
4 THE LAST COMMENT EXCEPT FOR THE FACT OF CONTEXT. AND  
5 SINCE THE PHYSICIAN IS NOT SEPARATED, IN OTHER WORDS,  
6 SINCE NO WALL OF SEPARATION HAS BEEN MADE IN THE REGS,  
7 THEN THE FACT THAT THE WOMAN HAS THE CHOICE IS SOMEWHAT  
8 PROBLEMATIC IN THAT SHE MIGHT NOT BE GETTING ALL THE  
9 INFORMATION THAT SHE NEEDS FROM HER PHYSICIAN. SO IT'S  
10 NOT SO MUCH -- AS SOMEONE WHO UNDERWENT IVF ALSO, THERE  
11 IS A CERTAIN EMOTIONAL STATE. AND YOU DO NEED TO TRUST  
12 YOUR PHYSICIAN COMPLETELY.

13 SO, THEREFORE, I DO TAKE ISSUE, THAT IT IS  
14 COMPLETELY HER DECISION; AND YET IF YOU LOOK AT THE  
15 CONTEXT UNDER WHICH THESE EGGS ARE BEING GIVEN, WITHOUT  
16 ANY SORT OF SEPARATION, IT IS PROBLEMATIC.

17 CO-CHAIR LO: SO JUST TO MAKE SURE I  
18 UNDERLINED YOUR POINT, THIS TIES IN WITH OTHER COMMENTS  
19 YOU'VE MADE GOING TO YOUR DESIRE TO SEE MORE SEPARATION  
20 BETWEEN THE PHYSICIAN DOING THE OOCYTE RETRIEVAL AND  
21 THE RESEARCHER. AND THE OBJECTION WAS THE EXCEPTION  
22 THAT WAS MADE IN THE FEBRUARY LANGUAGE, THAT THE IRB  
23 MAY APPROVE AN EXCEPTION.

24 MS. GREENFIELD: ABSOLUTELY. THANK YOU.

25 CO-CHAIR LO: OKAY. ALL RIGHT. IF THERE'S

1 NO FURTHER DISCUSSION, CAN I HEAR A MOTION ABOUT THIS  
2 LANGUAGE UNDER 7 TO ADOPT THE PROPOSED LANGUAGE?

3 DR. PRIETO: I MOVE WE ADOPT THIS WITH THE  
4 MODIFICATION UNDER 1(A), THAT UNDERGOING STIMULATION TO  
5 PRODUCE SHOULD BE REPLACED WITH THE WORD "PROVIDING."

6 CO-CHAIR LO: OOCYTES. AND ALSO FOR (B) AS  
7 WELL?

8 DR. PRIETO: YES.

9 MR. TOCHER: I JUST WANTED TO CLARIFY FOR THE  
10 RECORD THAT I DON'T BELIEVE THAT WE HAVE A QUORUM YET,  
11 AND SO THE VOTE MAY BE TAKEN FOR THE PURPOSES OF --

12 CO-CHAIR LO: THE SENSE OF THE COMMITTEE.  
13 LET'S JUST MAKE SURE. CAN YOU DO A HEAD COUNT FOR US,  
14 JENNIFER? JON SHESTACK HAS COME IN.

15 DR. KIESSLING: HOW MANY PEOPLE DO WE HAVE ON  
16 SPEAKER PHONE?

17 MS. ROSAIA: YOU HAVE TWO. YOU HAVE KEVIN  
18 AND YOU HAVE JOHN WAGNER, SO YOU HAVE A TOTAL OF  
19 ELEVEN, AND YOU NEED TWELVE FOR A QUORUM.

20 CO-CHAIR LO: SO WE DON'T HAVE A QUORUM, BUT  
21 WE CAN TAKE A SENSE OF THE WORKING GROUP.

22 MR. SHESTACK: WHAT IS A QUORUM HERE?

23 MS. ROSAIA: TWELVE.

24 MR. SHESTACK: TWELVE.

25 CO-CHAIR LANSING: THAT'S ALL RIGHT. WE CAN

1 SAY WE HAD ELEVEN AND WE WERE ONE SHORT OF A QUORUM.  
2 THIS IS A SENSE OF THE WORKING GROUP.

3 CO-CHAIR LO: AND THEN I THINK THE ICOC WILL  
4 NEED TO FACTOR IN THAT AS THEY DELIBERATE. SO A MOTION  
5 HAS BEEN MADE --

6 CO-CHAIR LANSING: SECOND.

7 CO-CHAIR LO: -- AND SECONDED. NO FURTHER --  
8 ANY FURTHER DISCUSSION? IF NOT, ALL THOSE IN FAVOR  
9 AYE. ANY DISAGREEMENTS? OKAY. THANK YOU.

10 THE NEXT ISSUE I'D LIKE TO TURN TO IS ON PAGE  
11 8 OF THIS HANDOUT, NO. 9 AND NO. 10. PAGE LOOKS LIKE  
12 THIS. THIS HAS TO DO WITH THE PERIOD OF DELIBERATIONS  
13 AND RECONTACT AFTER THAT DELIBERATION PERIOD. DOES  
14 EVERYBODY -- I KNOW WE'RE JUMPING AROUND. OKAY.

15 I'M GOING TO ACTUALLY JUST TRY AND SUMMARIZE  
16 THE PUBLIC COMMENTS. THERE WERE A NUMBER OF CONCERNS  
17 REGARDING OUR IDEA OF A PERIOD OF DELIBERATION AFTER  
18 THE WOMAN HAD RECEIVED INFORMATION, TALKED WITH HER  
19 PHYSICIAN AND THE RESEARCHER TO REQUIRE A DELIBERATION  
20 PERIOD BEFORE GIVING FINAL CONSENT.

21 AND THE CONCERNS HAD TO DO WITH GIVEN THAT WE  
22 ARE IMPOSING AN INNOVATIVE REQUIREMENT THAT THERE BE AN  
23 ASSESSMENT OF COMPREHENSION, THERE'S A LOT MORE  
24 ASSURANCE OF CONSENT IN THIS CONTEXT THAN OTHERS. AND  
25 THE OTHER CONCERN WAS THAT, AGAIN, THERE MAY BE SOME

1 WOMEN WHO ARE VERY, VERY WELL INFORMED TO WHOM A PERIOD  
2 OF DELIBERATION MAY NOT BE DESIRABLE. THEY MAY HAVE  
3 SCHEDULED IT IN THE FUTURE, THEY MAY BE -- EXAMPLES  
4 GIVEN IN A PREVIOUS MEETING THAT THERE ACTUALLY BE A  
5 SCIENTIST INVOLVED WITH THIS AND REALLY KNOW THIS AND  
6 HAVE THOUGHT ABOUT IT, AND SAY TO THEM, NO, YOU CAN'T  
7 DECIDE UNLESS A CERTAIN PERIOD OF TIME ELAPSES MAY BE  
8 DISRESPECTFUL TO THEM AS DECISION MAKERS.

9 SO THE PROPOSED CHANGES, THE PROPOSED CHANGE  
10 WE HAD WAS THAT RATHER THAN REQUIRING A PERIOD OF  
11 DELIBERATION BEFORE FINAL CONSENT, PROSPECTIVE DONORS  
12 SHALL BE INFORMED OF THEIR OPTIONS TO DELIBERATE BEFORE  
13 DECIDING WHETHER OR NOT TO GIVE CONSENT. SO LET'S TAKE  
14 THAT ONE FIRST, AND THEN THERE'S ANOTHER COMMENT THAT'S  
15 TIED TO THAT THAT WE'LL GET TO LATER. SO THIS IS NOT  
16 REALLY MAKING DELIBERATION MANDATORY, BUT TO GIVE THE  
17 WOMAN A CHOICE TO HAVE THE DELIBERATION PERIOD OR NOT.

18 CO-CHAIR LANSING: THIS WAS AN ISSUE THAT GOT  
19 A LOT OF COMMENT FROM THE PUBLIC WHICH I FOUND ACTUALLY  
20 QUITE FASCINATING BECAUSE WE, AS A GROUP, WERE TRYING  
21 TO -- HOW DO I SAY THIS? -- GO TO THE MOST EXTREME  
22 POSITION, DO YOU KNOW, LIKE GIVING THE MOST TIME THAT  
23 WE COULD THINK OF WITHOUT IMPEDING THE PROCESS AND  
24 WITHOUT MAKING IT BUREAUCRATIC, AND ALWAYS ERRING ON  
25 THAT SIDE, DO YOU KNOW, AS I THINK WE'VE DONE

1 THROUGHOUT ALL OF OUR DELIBERATIONS. AND IT WAS  
2 FASCINATING TO ME THAT WE GOT THE COMMENTS THAT WE DID.

3 I ACTUALLY THINK THIS IS A VERY GOOD SOLUTION  
4 TO THE THING BECAUSE, AGAIN, I COME BACK TO A WOMAN'S  
5 RIGHT TO MAKE THESE DECISIONS OR THE DONOR'S RIGHT TO  
6 MAKE THESE DECISIONS. AND THIS GIVES YOU THE CHOICE.  
7 THIS SAYS TO YOU, OKAY, YOU CAN TAKE THE MAXIMUM  
8 AMOUNT, BUT YOU'RE NOT REQUIRED TO. YOU CAN WAIVE  
9 THAT.

10 AND IT SEEMS TO ME ACTUALLY AN INCREDIBLY  
11 INTELLIGENT WAY TO LOOK AT THE ISSUE. SO I, AGAIN,  
12 THANK THE PUBLIC FOR THEIR COMMENT AND INITIALLY, YOU  
13 KNOW, WAS HOLDING ONTO THE MORE, I GUESS YOU WOULD SAY,  
14 EXTREME VIEW. AND NOW I FEEL VERY COMFORTABLE THAT  
15 THIS GIVES THE DONOR THE RIGHT OF CHOICE.

16 CO-CHAIR LO: OTHER COMMENTS?

17 MS. CHARO: ALSO JUST FOR THE SAKE OF  
18 CLARIFICATION, I THINK IT'S WORTH NOTING THAT THIS  
19 PROVISION DOES NOT CREATE ANY NEW RIGHTS OR  
20 REQUIREMENTS. IT INFORMS PEOPLE OF SOMETHING THAT THEY  
21 ALWAYS HAD. YOU'RE ALWAYS ENTITLED TO SAY I'M NOT  
22 READY TO DECIDE. AND ALL THIS IS DOING IS REMINDING  
23 PEOPLE THAT THEY HAVE THAT RIGHT ALREADY.

24 CO-CHAIR LANSING: AND YOU'RE ALSO, JUST TO  
25 ADD, ALWAYS ENTITLED IN MOST SITUATIONS TO SAY I WAIVE

1 THAT RIGHT. DO YOU KNOW? I WISH TO ACT SOONER.

2 CO-CHAIR LO: OTHER COMMENTS, THOUGHTS ON  
3 THIS? THOSE ON THE PHONE, KEVIN, ZACH, ANY COMMENTS ON  
4 THIS? COMMENTS FROM MEMBERS OF THE AUDIENCE THAT ARE  
5 HERE? OKAY.

6 DR. HALL: WE THINK IT'S FINE HERE, BERNIE.

7 CO-CHAIR LO: THANKS, ZACH. LET ME THEN  
8 PROCEED TO SORT OF THE SECOND PART, NO. 10, ON THE  
9 BOTTOM OF THE PAGE. SO ONCE WE'VE THOUGHT ABOUT THIS  
10 DELIBERATION PERIOD, FOR NOW MAKING IT OPTIONAL --  
11 WHICH WE NOW MAY WANT TO MAKE OPTIONAL. QUESTION IS  
12 AFTER THAT DELIBERATION PERIOD, HOW IS RECONTACT  
13 REINSTITUTED? AND, AGAIN, I THINK THIS ACTUALLY GOES  
14 BACK TO ANN'S PRESENTATION AT ONE OF OUR VERY EARLY  
15 MEETINGS WHERE SHE POINTED OUT THAT IT'S UP TO THE  
16 PROSPECTIVE DONOR TO RECONTACT THE RESEARCH TEAM AND  
17 SAY, "I'M STILL INTERESTED. WHAT'S THE NEXT STEP?"

18 THAT CREATES LESS PRESSURE THAN IF THE  
19 RESEARCHER CALLED UP AND SAID, "HEY, DO YOU THINK YOU'D  
20 LIKE TO CONSENT NOW?" SO WE ORIGINALLY SUGGESTED THAT  
21 THE REGULATIONS REQUIRE THE WOMEN -- THE DONOR TO MAKE  
22 RECONTACT. AND AGAIN, IT WAS POINTED OUT THAT SOME  
23 DONORS MAY ACTUALLY PREFER THE RESEARCHERS TO CONTACT  
24 THEM; AND RATHER THAN REQUIRING WHAT WE PERCEIVE TO BE  
25 A PROTECTION, AS A RESTRICTION THAT WE INTERPRET AS A



1 PROTECTION, TO MAKE IT OPTIONAL TO MAKE SURE WOMEN  
2 UNDERSTOOD THAT THEY COULD CHOOSE TO NOT HAVE THE  
3 RESEARCHERS RECONTACT THEM, BUT THEY COULD WAIVE THAT  
4 AND THEY COULD CHOOSE TO HAVE RESEARCHERS MAKING THE  
5 RECONTACT.

6 SO, AGAIN, I THINK, AS SHERRY SAID, WE'RE  
7 TAKING A PRINCIPLE, MAKING SURE WOMEN ARE AWARE OF THIS  
8 RIGHT TO CONTROL HOW THEY'RE RECONTACTED, BUT MAKING IT  
9 OPTIONAL AND GIVING THEM THE CHOICE OF SAYING, "NO, I'D  
10 RATHER HAVE THE RESEARCHERS CONTACT ME."

11 SO COMMENTS, SUGGESTIONS ON THIS ONE?

12 DR. TAYLOR: BERNIE, I'D LIKE TO MAYBE  
13 SUGGEST ANOTHER AND PERHAPS A LITTLE BIT MORE  
14 BUREAUCRATIC DEGREE OF SEPARATION. AND THAT WOULD BE  
15 TO HAVE THE IRB MAKE THE CONTACT RATHER THAN THE  
16 RESEARCHER PER SE. SO I WOULD SUGGEST THAT IF THE  
17 DONOR-PATIENT-SUBJECT HAS NOT CONTACTED THE  
18 INVESTIGATOR, AND THE INVESTIGATOR WANTS TO SORT OF SEE  
19 WHETHER THAT INDIVIDUAL IS STILL WILLING TO PARTICIPATE  
20 TO COME BACK TO PROVIDE FURTHER INFORMATION OR DATA, I  
21 THINK RATHER THAN HAVING THE INVESTIGATOR GO DIRECTLY  
22 TO THE SUBJECT, IT SEEMS MORE APPROPRIATE THAT THE  
23 INVESTIGATOR WOULD GO TO THE IRB COMMITTEE AND ASK THE  
24 IRB COMMITTEE TO MAKE CONTACT WITH THE PATIENT.

25 ADMITTEDLY, IT'S ANOTHER STEP IN THE PROCESS,

1 BUT I THINK IT PROVIDES SOME SEPARATION FROM  
2 PARTICULARLY SORT OF SCIENTIFIC INVESTIGATORS THAT MAY  
3 BE QUITE FAR FROM THE PATIENT'S CONTACT WITH THE  
4 EXCEPTION OF THE INITIAL CONSENT TO THE RESEARCH  
5 PROTOCOL. SO THAT WAS A THOUGHT THAT I HAD.

6 CO-CHAIR LO: LET ME CLARIFY HOW I THINK THIS  
7 WORKS. I'M NOT SURE. IT MAY BE DIFFERENT FROM WHAT I  
8 HEAR YOU SAYING, ROB. SO I THINK THIS PROPOSES THAT WE  
9 SAY TO THE WOMAN YOU'VE DECIDED TO HAVE SOME WAITING  
10 PERIOD, AS IS YOUR RIGHT. NOW WE WANT TO OFFER YOU  
11 OPTIONS WHEN THAT WAITING PERIOD EXPIRES. WHO DO YOU  
12 WANT TO INITIATE CONTACT? DO YOU WANT TO MAKE CONTACT?  
13 ARE YOU WILLING TO HAVE THE RESEARCHER CONTACT YOU?

14 DR. TAYLOR: I'M SORRY.

15 CO-CHAIR LO: IF YOU ONLY WANT THE FIRST, NO  
16 ONE WILL CONTACT YOU.

17 DR. TAYLOR: I WAS --

18 CO-CHAIR LO: SO, YOU KNOW, I GUESS WE CAN  
19 INCLUDE THE IRB IN THAT, BUT I'M NOT SURE HAVING THE  
20 IRB IN THE PICTURE IF THE WOMAN SAYS LET THE RESEARCHER  
21 CONTACT ME.

22 DR. TAYLOR: LET ME -- I WAS ACTUALLY -- I  
23 WAS THINKING NOT ABOUT THIS PARTICULAR SITUATION, BUT  
24 MORE ABOUT IF MORE INFORMATION WERE REQUIRED. SO --

25 CO-CHAIR LO: THIS IS JUST THE UP-FRONT.

1 DR. TAYLOR: THIS IS THE UP-FRONT  
2 DELIBERATION PERIOD. SO DELETE EVERYTHING I PREVIOUSLY  
3 SAID EVER.

4 CO-CHAIR LO: I THOUGHT IT MIGHT BE A  
5 DIFFERENT SET OF ISSUES. ANY OTHER COMMENTS ON PART B?  
6 OKAY. COMMENTS FROM THOSE ON THE PHONE, QUESTIONS,  
7 JOHN, ZACH, OR KEVIN? SILENCE MEANS YOU'RE FALLING  
8 ASLEEP.

9 DR. HALL: NO COMMENTS ON THIS END.

10 CO-CHAIR LO: ARE WE COMING THROUGH OKAY?  
11 ARE YOU HEARING US OKAY?

12 DR. HALL: PRETTY WELL.

13 CO-CHAIR LO: AND, AGAIN, I INVITE COMMENTS  
14 FROM MEMBERS OF THE PUBLIC. AGAIN FOR THE RECORD,  
15 PLEASE INTRODUCE YOURSELF.

16 MR. REED: DON REED, CALIFORNIANS FOR CURES.  
17 DO I UNDERSTAND CORRECTLY THAT IT'S POSSIBLE THAT THE  
18 RESEARCHER WOULD AT NO POINT BE ALLOWED TO TALK TO THE  
19 PERSON MAKING THE DONATION?

20 CO-CHAIR LO: NO. THIS IS -- LET ME JUST  
21 MAKE SURE WE'VE GOT THIS CLEAR. THEY'VE HAD AN INITIAL  
22 DISCUSSION. THE WOMAN SAYS THANK YOU. NOW I WISH TO  
23 EXERCISE MY RIGHT TO HAVE A DELIBERATION PERIOD.

24 MR. REED: BUT THE RESEARCHER, HIM OR  
25 HERSELF, HAS HAD A CHANCE TO SAY EXACTLY WHAT THE

1 IMPORTANCE --

2 CO-CHAIR LO: RIGHT. THIS IS AFTER SHE'S  
3 RECEIVED INFORMATION, AND NOW SHE'S MADE THE CHOICE,  
4 BEFORE MAKING THE FINAL DECISION TO DONATE OR NOT,  
5 WANTS SOME TIME TO THINK ABOUT IT. THIS ONLY GOES TO  
6 DOES SHE WANT THE RESEARCHER TO RECONTACT HER AFTER  
7 THAT DELIBERATION PERIOD, OR DOES SHE WANT TO INITIATE  
8 CONTACT.

9 DR. OLDEN: I THINK I WOULD BE MORE  
10 COMFORTABLE WITH -- I KNOW, GEOFF, WE APPROVED THE  
11 COMMENT. I THINK THE INVESTIGATOR CONTACTING THE  
12 PERSON DIRECTLY WOULD IN SOME CASES INTIMIDATE,  
13 POSSIBLY, THE DONOR. SO I'M A LITTLE UNCOMFORTABLE  
14 WITH THAT, EVEN THOUGH I WOULD BE MORE IN FAVOR OF  
15 HAVING SOME SORT OF INTERMEDIATE GROUP, SUCH AS THE  
16 IRB, CONTACT THE PERSON, SO I'M A LITTLE UNCOMFORTABLE.

17 CO-CHAIR LO: AGAIN, LET ME CLARIFY. THIS IS  
18 EVEN AFTER THE WOMAN HERSELF HAS SAID THE RESEARCHER  
19 MAY CONTACT ME AFTER THIS PERIOD OF TIME.

20 DR. OLDEN: WELL, I WOULDN'T LIKE FOR THAT TO  
21 BE PRESENTED TO THE DONOR AS AN OPTION. I THINK THE  
22 OPTION SHOULD BE AFTER THE DELIBERATION PERIOD, THAT  
23 SHE BE OFFERED THE OPPORTUNITY FOR THE IRB TO CONTACT  
24 HER AS AN INTERMEDIARY.

25 CO-CHAIR LO: OTHER COMMENTS, THOUGHTS ON

1 THAT?

2 DR. KIESSLING: WE'RE THE ONES THAT HAVE  
3 THIS --

4 MS. CHARO: I'M SENSITIVE TO THIS ISSUE OF  
5 PEOPLE FEELING INTIMIDATED BECAUSE POLITENESS OFTEN  
6 PREVENTS US FROM SAYING WHAT WE WOULD LIKE TO SAY. SO  
7 I'M TRYING TO THINK ABOUT THIS KIND OF -- I'M TRYING TO  
8 THINK ABOUT THIS IN A CHRONOLOGICAL FASHION, RIGHT. SO  
9 I'M THERE, I'M CONTEMPLATING A DONATION, AND I SAY, YOU  
10 KNOW, I'M JUST NOT READY TO DECIDE YET, SO I'M GOING TO  
11 TAKE A LITTLE WHILE. OKAY, FINE. THAT'S YOUR RIGHT,  
12 LIKE WE TOLD YOU. AND THEN THEY SAY, YOU KNOW, WILL  
13 YOU CALL US OR SHALL WE CALL YOU, RIGHT.

14 AND SO FIRST QUESTION IS DO YOU THINK THAT  
15 PEOPLE ARE GOING TO BE RELUCTANT UNDER THOSE  
16 CIRCUMSTANCES AND SAY, YOU KNOW, I'LL GET IN TOUCH WITH  
17 YOU. RIGHT. I'M TRYING TO THINK THAT THROUGH. I'VE  
18 GOT TO SAY THAT KIND OF I'LL CALL YOU IS MY TYPICAL  
19 WAY -- I'M SORRY I'M REVEALING THIS NOW FOR ALL TIME --  
20 OF GETTING RID OF FOLKS. AND I'M SURE I'M NOT ALONE IN  
21 THAT. THAT IS MY GENTLE BRUSHOFF.

22 AND SO I'M TRYING TO THINK ABOUT WHETHER THAT  
23 IS STILL TOO INTIMIDATING FOR PEOPLE BECAUSE THAT'S AN  
24 EASY OUT THAT I WOULD EXPECT A LOT OF PEOPLE TO TAKE.  
25 IF THEY'RE SO POLITE THAT THEY CAN'T SAY THAT AND SAY

1 YOU CAN GET IN TOUCH WITH ME, OF COURSE, THE FIRST TIME  
2 SOMEBODY GETS IN TOUCH WITH THEM, THEY CAN SAY I'M  
3 STILL NOT READY TO DECIDE. I'LL CALL YOU. SO WHAT  
4 WE'RE ASKING IS WHETHER OR NOT THE CONSTANT ABILITY TO  
5 SAY I'LL CALL YOU IS INSUFFICIENT HERE.

6 AND THE REASON I'M HESITATING IS BECAUSE THE  
7 ALTERNATIVE, WHICH IS THIS IRB, RAISES QUESTIONS  
8 WHETHER OR NOT THAT'S WHAT IRB'S ARE USUALLY DOING.  
9 I'VE SEEN LOTS OF PROTOCOLS THAT INVOLVE CONTACT AND  
10 RECONTACT, AND IT'S -- I DON'T RECALL EVER SEEING ONE  
11 WHERE THE IRB ACTUALLY HANDLED THAT. I'VE SEEN IT  
12 WHERE A SUBJECT'S PERSONAL PHYSICIAN ACTED AS  
13 INTERMEDIARY. BUT, IF ANYTHING, I CAN IMAGINE SOME  
14 PEOPLE MIGHT THINK THAT'S EVEN MORE PROBLEMATIC RATHER  
15 THAN LESS IN THIS PARTICULAR SITUATION, SO I'M  
16 RELUCTANT TO BEGIN TO OFFER THAT AS AN ALTERNATIVE.

17 SO SINCE IT'S NOT A TRADITIONAL IRB ROLE, I'M  
18 STRUGGLING HERE, A, HOW LIKELY IT IS PEOPLE WILL  
19 CONTINUE TO BE INCAPABLE OF SAYING I'LL GET IN TOUCH  
20 WITH YOU, AND ALSO WHO THE RIGHT INTERMEDIARY REALLY  
21 WOULD BE IF WE FELT WE NEEDED IT.

22 CO-CHAIR LANSING: I HAVE A QUESTION BECAUSE  
23 I'M A CONFUSED. SO A WOMAN IS INFORMED OF ALL HER  
24 RIGHTS. SHE SAYS I WANT TO TAKE SOME TIME. AND THEN  
25 WHAT YOU'RE RAISING IS WHETHER OR NOT IF SOMEBODY GETS

1 IN TOUCH WITH THAT WOMAN, THAT IT MAKES HER FEEL  
2 INTIMIDATED AND IT MAKES HER FEEL PRESSURED. SO THEN  
3 THE ALTERNATIVE WOULD BE JUST TO SAY -- I'M MAKING THIS  
4 UP -- AND THEN THE WOMAN WILL CALL US WHEN SHE'S READY.  
5 THAT WOULD BE -- SHE WILL THEN CALL YOU OR NEVER CALL  
6 YOU AGAIN.

7 DR. OLDEN: MY CONCERN IS THAT THE RESEARCHER  
8 GETTING IN CONTACT WITH HER WOULD BE, IN A SENSE, IN  
9 SOME CASES, INTIMIDATING OR PRESSURE. I'M A LITTLE  
10 CONCERNED, NOT --

11 CO-CHAIR LANSING: YOU MAY BE RIGHT.

12 DR. KIESSLING: ONE OF THE REASONS THAT WE  
13 SORT OF FOLLOW THIS THE DONOR CONTACTS THE PROGRAM RULE  
14 IS THERE WAS A STUDY THAT WAS DONE THAT INDICATED THAT  
15 THERE WERE A SURPRISING NUMBER OF PEOPLE WHO WERE  
16 ENCOURAGED TO DONATE THEIR KIDNEYS TO FAMILY MEMBERS  
17 THAT DIDN'T REALLY WANT TO DO IT. THE WHOLE FAMILY WAS  
18 SAYING YOU'RE NOT DOING ANYTHING AND UNCLE GEORGE IS  
19 DYING, RIGHT. AND WE GOT VERY CONCERNED ABOUT THAT,  
20 VERY CONCERNED THAT THERE WAS SOMEONE IN THIS DONOR'S  
21 WORLD WHO HAD A SERIOUS DISEASE, AND THAT BECAUSE IT  
22 WAS THAT KIND OF PRESSURE THAT WAS HAVING HER COME  
23 FORWARD. AND IT SEEMED TO ME THAT WHAT THIS INDIVIDUAL  
24 DID NOT NEED WAS ANY MORE PRESSURE FROM ANYONE.

25 AND SO IT WAS FOR THAT REASON THAT WE

1 DECIDED, ALL RIGHT, IF SHE REALLY WANTS TO DO THIS,  
2 THEN SHE WILL CONTINUE THE PROCESS AND SHE WILL CONTACT  
3 THE RESEARCH TEAM AGAIN HERSELF. IF THE RESEARCH TEAM  
4 CONTACTS HER, IT'S JUST ONE MORE LEVEL OF PRESSURE ON  
5 THIS DECISION PROCESS.

6 CO-CHAIR LANSING: YOU'RE RIGHT AND YOU'RE  
7 BOTH SAYING THE SAME THING.

8 CO-CHAIR LO: THIS IS THE REASONING THAT LED  
9 US TO ADOPT THIS CLAUSE IN THE FIRST PLACE, SAYING THE  
10 WOMAN, PROSPECTIVE DONOR, HAS TO INITIATE THE CONTACT.  
11 WE ALWAYS HAVE THE OPTION OF SAYING WE AGREE WITH WHAT  
12 WE RECOMMENDED IN FEBRUARY, AND WE DON'T WANT TO CHANGE  
13 IT BEYOND THAT AT THIS TIME. AND AGAIN, WE CAN ALWAYS  
14 COME BACK TO IT LATER. A LOT OF WOMEN SAY, YOU KNOW,  
15 THIS IS RIDICULOUS MY HAVING TO CALL YOU GUYS BECAUSE  
16 THEN I LEAVE A MESSAGE, YOU HAVE TO CALL ME BACK,  
17 WHATEVER.

18 CO-CHAIR LANSING: I ACTUALLY THINK YOU'RE  
19 RIGHT. IF WE GET A CALL FROM SOMEONE SAYING, WELL, YOU  
20 MADE YOUR MIND UP YET, YOU KNOW, IT'S A SUBTLE FORM OF  
21 PRESSURE. I DIDN'T REALLY THINK ABOUT THIS, BUT I  
22 THINK YOU'RE RIGHT. IT'S A SUBTLE FORM OF PRESSURE,  
23 AND I DON'T THINK WE NEED IT.

24 DR. PRIETO: IT SEEMS TO ME, THOUGH, EVEN  
25 WITH THIS MODIFIED LANGUAGE, AREN'T WE STILL GIVING THE



1 WOMAN THE OPTION OF THAT APPROACH, OF SAYING DON'T CALL  
2 ME. I WANT TO MAKE UP MY MIND, AND I WILL CALL YOU,  
3 AND ONLY REQUESTING A REMINDER CALL IF THAT'S WHAT SHE  
4 WANTS.

5 CO-CHAIR LO: AGAIN, I THINK WHAT A NUMBER OF  
6 PEOPLE HAVE SAID IS THE SUBTLE PRESSURES THAT ARE  
7 CONVEYED WHERE SOMEONE COULD SAY WE'RE VERY COMFORTABLE  
8 WITH YOUR CHOOSING A WAITING PERIOD; BUT WHEN THAT  
9 WAITING PERIOD IS UP, HOW SHALL WE GET BACK IN TOUCH.  
10 IS IT OKAY IF WE CALL YOU, OR DO YOU WANT TO CONTACT  
11 US? YOU CAN SORT OF SUGGEST THAT YOU REALLY WANT TO  
12 LET US CALL YOU. AND I GUESS THE CONCERN THAT'S BEEN  
13 RAISED IS THAT MAKE IT EASY FOR THE WOMAN TO SAY NO BY  
14 JUST NOT DOING ANYTHING.

15 SO I GUESS IT'S -- WE'VE HEARD -- IT STRIKES  
16 ME THAT ORIGINALLY WE WANTED TO PUT THIS IN AND HEARD  
17 SEVERAL COMMENTS, ALL SUGGESTING THERE'S VALUE TO THAT.  
18 I'M NOT SURE THERE'S A COMPELLING ARGUMENT ON THE OTHER  
19 SIDE TO SAY NO, NO, YOU'RE HURTING WOMEN, PROSPECTIVE  
20 DONORS, BY NOT ALLOWING THEM TO HAVE THE RESEARCHER  
21 CONTACT THEM FIRST.

22 MS. CHARO: MY UNDERSTANDING WAS THE FEAR WAS  
23 THAT IF WE ABSOLUTELY PROHIBIT THE RECONTACT, THAT  
24 THERE WILL BE PEOPLE WHO ACTUALLY WOULD HAVE BEEN  
25 PERFECTLY HAPPY TO DONATE, BUT JUST WON'T GET AROUND TO

1 IT. SO THAT WAS THE COST OF THIS. IT WAS THE MARGINAL  
2 LOSS OF POTENTIAL DONORS. AND THE GAIN WAS THE CLARITY  
3 OF YOU MAY NOT RECONTACT ME. WHEN SOMEBODY WALKS OUT  
4 YOUR DOOR, THEY'RE GONE UNTIL THEY GET IN TOUCH WITH  
5 YOU. I DON'T KNOW THAT ANYBODY HAS ANY WAY OF  
6 ESTIMATING REALLY WHAT THE MARGINAL LOSS OF DONORS  
7 WOULD BE UNDER THOSE CIRCUMSTANCES, AND I DON'T KNOW  
8 THAT ANYBODY HAS ANY WAY OF QUANTIFYING THE DEGREE OF  
9 PRESSURE, SO I'M FEELING KIND OF STUCK HERE.

10 DR. KIESSLING: WE'VE NEVER LOST ANY.

11 MS. CHARO: AND HAVE YOU RECONTACTED?

12 DR. KIESSLING: FOR PEOPLE THAT YOU DON'T  
13 HEAR FROM FOR A VERY LONG PERIOD OF TIME, ONCE IN A  
14 WHILE THE COORDINATOR WILL GO THROUGH THE LIST AND SAY  
15 WE'RE UPDATING OUR ACTIVE/INACTIVE LIST. YOU  
16 FREQUENTLY GET SOMEBODY'S VOICE MAIL. IF THEY DON'T  
17 GET BACK TO YOU IN A WEEK OR TWO, THEN THEY'RE NOT  
18 ACTIVE ANYMORE.

19 CO-CHAIR LANSING: I ACTUALLY AM LEANING NOW  
20 VERY STRONGLY TO LEAVING IT ALONE. I'LL TELL YOU WHY.  
21 WE JUST DON'T WANT ANY LOOPHOLES FOR ERRORS. AND THIS  
22 COULD EXPOSE US TO SOMETHING UNINTENTIONALLY. AN  
23 OVERAGGRESSIVE PERSON CAN GET ON THE PHONE AND SAY, YOU  
24 KNOW, THEIR VOICE TONE AND PERHAPS A LOT MORE THAN  
25 THAT. YOU KNOW, THIS IS REALLY FOR THE GOOD OF

1 EVERYTHING, YOU KNOW. HAVE YOU MADE UP YOUR MIND YET,  
2 WHATEVER. AND WE'RE LEAVING OURSELVES THE POSSIBILITY  
3 OF A LOOPHOLE FOR A PERSON -- I JUST CAN'T IMAGINE  
4 SOMEONE WHO'S SERIOUSLY CONSIDERING THIS WHO WILL  
5 FORGET TO CALL, DO YOU KNOW, OR WHO WILL GET  
6 FRUSTRATED. THEY FORGOT TO CALL, THEN MY INSTINCT IS  
7 THEY SHOULDN'T. FORGETTING TO CALL, AS FREUD WOULD  
8 SAY, THAT'S YOUR ANSWER RIGHT THERE. DO YOU KNOW?

9 I ACTUALLY THINK, ESPECIALLY NOW AS WE'RE  
10 SETTING THIS UP, I MEAN IF WE LOSE SOMEBODY, IT WOULD  
11 BE SAD, BUT FAR WORSE IF SOMEBODY PUTS PRESSURE AND  
12 THEN, YOU KNOW, THAT TO ME IS A MORE DANGEROUS PROBLEM.

13 CO-CHAIR LO: SO ANY ADDITIONAL COMMENTS FROM  
14 THOSE ON THE PHONE? ANY COMMENTS FROM THOSE MEMBERS OF  
15 THE PUBLIC HERE? OKAY.

16 SO I'M GOING TO SPLIT THIS. WHAT I'M HEARING  
17 IS ON NO. 9, THAT THIS IS -- LET'S DO IT  
18 CHRONOLOGICALLY. THE PROSPECTIVE DONOR HAS BEEN  
19 INFORMED OF THEIR OPTIONS TO DELIBERATE BEFORE DECIDING  
20 WHETHER OR NOT TO CONSENT. I'D LIKE TO HEAR A MOTION  
21 THAT WE ADOPT THE PROPOSED CHANGES.

22 MS. CHARO: SO MOVED.

23 DR. TAYLOR: SECOND.

24 CO-CHAIR LO: SECONDED. ALL THOSE IN FAVOR  
25 SAY AYE. ANY OPPOSED? OKAY.

1                   AND THEN FOR THE SECOND PART, PROSPECTIVE  
2                   DONORS SHALL BE INFORMED OF THEIR OPTION TO DELIBERATE.  
3                   PERHAPS IN LIGHT OF THE RECENT DISCUSSION, COULD  
4                   SOMEONE MAKE A MOTION THAT WE NOT MODIFY OUR ORIGINAL  
5                   LANGUAGE?

6                   CO-CHAIR LANSING:   SO MOVED.

7                   MS. CHARO:   WELL --

8                   DR. PRIETO:   DO WE NEED A MOTION TO NOT  
9                   MODIFY?

10                  CO-CHAIR LO:   OH, I'M SORRY.  I GUESS NOT.

11                  MS. CHARO:   BERNIE, WE DON'T HAVE ORIGINAL  
12                  LANGUAGE TO REVERT TO IS THE PROBLEM.

13                  MR. LOMAX:   I HAVE A SUGGESTION.

14                  CO-CHAIR LO:   IN CASE OF SUCH PERIODS OF  
15                  DELIBERATION, RESEARCHERS MAY NOT SOLICIT POTENTIAL  
16                  DONORS UNTIL THEY HAVE INITIATED RECONTACT WITH THE  
17                  RESEARCHERS.

18                  MS. CHARO:   I THOUGHT WE HAD DELETED THAT  
19                  ENTIRE SECTION, SO THAT WE DON'T HAVE TO RECREATE  
20                  SOMETHING TO FOLLOW ON THE NEW THREE.

21                  MR. LOMAX:   I CAN GIVE YOU A SUGGESTION.  IF  
22                  I UNDERSTAND THE SENSE OF THE COMMITTEE, YOU WOULD TAKE  
23                  THE SECOND THREE, PROSPECTIVE DONORS SHALL BE INFORMED  
24                  OF THEIR OPTION TO DELIBERATE BEFORE DECIDING WHETHER  
25                  OR NOT TO GIVE CONSENT.  FULL STOP.  IF PROSPECTIVE

1 DONORS CHOOSE A DELIBERATION PERIOD, THE DONOR SHALL  
2 INITIATE RECONTACT.

3 MS. CHARO: NO. YOU CAN'T TELL THE DONOR SHE  
4 HAS TO.

5 CO-CHAIR LO: RESEARCHERS MAY NOT SOLICIT --  
6 MR. LOMAX: THAT'S RIGHT.

7 CO-CHAIR LO: -- POTENTIAL DONORS UNTIL THEY  
8 HAVE INITIATED RECONTACT WITH THE RESEARCHER. OKAY.  
9 SOMEONE LIKE TO MOVE THAT LANGUAGE?

10 CO-CHAIR LANSING: SO MOVED.

11 DR. OLDEN: SECOND.

12 CO-CHAIR LO: ALL THOSE IN FAVOR OF THIS NEW  
13 LANGUAGE. ANY OBJECTION?

14 MS. CHARO: REGISTER ABSTENTION FOR THOSE  
15 STILL CONFUSED.

16 CO-CHAIR LO: OKAY. YOU WANT A  
17 CLARIFICATION?

18 MS. CHARO: NO. I'M NOT COMPLETELY  
19 PERSUADED, BUT I'M NOT GOING TO STAND AROUND AND STAMP  
20 MY FOOT.

21 CO-CHAIR LO: OKAY. THANK YOU. THE NEXT  
22 ISSUE --

23 CO-CHAIR LANSING: PUBLIC COMMENT?

24 CO-CHAIR LO: I ASKED BUT --

25 CO-CHAIR LANSING: THERE WAS NO PUBLIC

1 COMMENT.

2 CO-CHAIR LO: -- THERE WAS NO PUBLIC COMMENT.  
3 THE NEXT ISSUE I'D LIKE TO TURN TO, AND, GEOFF, I'M  
4 GOING TO ASK YOUR HELP IN FINDING IT, IS DONATION OF  
5 FETAL TISSUE AND CORD BLOOD FOR STEM CELLS. AND THAT'S  
6 ON PAGE 9, NO. 11. AND THE COMMENT WAS THAT CORD  
7 BLOOD -- THERE'S ONE FOR CORD BLOOD AND ONE FOR --  
8 OKAY. SO FOR CORD BLOOD, NO. 11, THE COMMENT FROM THE  
9 PUBLIC WAS THE CONSENT FROM EACH PARENT. AGAIN, HERE'S  
10 THE SITUATION THAT THE WOMAN AFTER LABOR WANTS TO  
11 DONATE THE CORD BLOOD OR THE PLACENTA, I GUESS, FOR  
12 CIRM-FUNDED RESEARCH.

13 NOW, SHE ALREADY HAS THE OPTIONS OF EITHER  
14 DISCARDING IT, DONATING IT TO A CORD BLOOD BANK EITHER  
15 A FOR-PROFIT ONE OR NOT-FOR-PROFIT ONE; BUT NOW IF SHE  
16 DOES DECIDE, HOWEVER, TO DONATE FOR CIRM-FUNDED  
17 RESEARCH, THE CURRENT REQUIREMENT IN THE FEDERAL  
18 REGULATIONS IS THAT BOTH BIOLOGICAL PARENTS HAVE TO  
19 GIVE CONSENT. AND THE REASON FOR THAT WAS THAT WE HAD  
20 ESTABLISHED, I THINK, A GENERAL PRINCIPLE THAT STEM  
21 CELL RESEARCH IS DIFFERENT THAN OTHER KINDS OF RESEARCH  
22 BECAUSE DNA IS PROPAGATED IN THE LABORATORY FOR A LONG  
23 TIME, IT CAN BE TRANSPLANTED INTO ANIMALS, INTO  
24 EVENTUALLY, WE HOPE, HUMANS FOR THERAPY.

25 AND THAT THERE'S SOME PEOPLE WHO MAY AGREE TO

1 RESEARCH IN GENERAL WHO MAY BALK AT THOSE USES OF STEM  
2 CELL LINES DERIVED USING THEIR GENETIC MATERIAL. SO  
3 THAT IN ALL OTHER SITUATIONS, SUCH AS AN OOCYTE DONOR  
4 AND EGG DONOR WHO'S NOT THE BIRTHING PARENT OR THE  
5 REARING PARENT, WE PUT A REQUIREMENT TO GO BACK TO THE  
6 GENETIC PARENT. HOWEVER, THE COMMENT FROM THE PUBLIC  
7 IS THAT CONSENT FROM EACH PARENT IS DIFFICULT AND NOT  
8 CONSISTENT WITH THE EXISTING PRACTICE FOR CONSENT OF  
9 STORAGE OF CORD BLOOD, WHICH IS THAT THE WOMAN ALONE  
10 CAN MAKE THAT DECISION.

11 STAFF HAS ADDED AN INTERESTING NOTE, THAT THE  
12 CANADIAN REGULATIONS HAVE RECENTLY HAD THE STIPULATION  
13 THAT FOR DONATION OF UMBILICAL CORD AND PLACENTAL  
14 TISSUE FOR DERIVATION OF STEM CELL LINES, THERE NEEDS  
15 TO BE FREE AND INFORMED CONSENT FROM THE MOTHER OR FROM  
16 BOTH PARENTS OF THE NEWBORN IF THERE ARE TWO PEOPLE  
17 COMMITTED TO PARENTING. SO THEY GO TO THE REARING  
18 PARENTS AS TO THE GENETIC PARENTS.

19 SO I THINK IT'S A COMPLICATED ISSUE BECAUSE  
20 THIS IS ONE OF THOSE COMPLICATED SITUATIONS WHERE MY  
21 OLD-FASHIONED NOTION OF WHO'S A PARENT GETS FRAGMENTED  
22 INTO DIFFERENT KINDS OF PARENTS, GENETICS, GESTATION,  
23 AND CHILDREARING. SO THIS IS SOMETHING I THINK IS  
24 WORTH OUR ATTENTION. AND I WANT TO OPEN TO COMMENT AND  
25 THOUGHTS.

1 DR. PRIETO: I GUESS I'M NOT SURE I  
2 UNDERSTAND WHY THE REARING PARENT IS BEING ASKED TO  
3 WEIGH IN ABOUT THE HANDLING OF GENETIC MATERIAL THAT IS  
4 NOT HIS. WHAT INTEREST DOES HE HAVE THERE? JUST A  
5 QUESTION.

6 MS. CHARO: WELL, YOU KNOW, THE REASON I FIND  
7 THIS SECTION COMPLICATED IS THAT THE CORD BLOOD HAS TWO  
8 DISTINCTLY DIFFERENT USES, AND THE TWO DIFFERENT USES  
9 IMPLICATE DIFFERENT DECISION MAKERS. AND THIS EXISTING  
10 SECTION TRIED TO INCORPORATE ALL OF THOSE POSSIBLE  
11 DECISION MAKERS BECAUSE WE COULDN'T EX ANTE KNOW WHICH  
12 OF THE USES FOR THE CORD BLOOD WOULD, IN FACT, WIND UP  
13 IN PLAY.

14 SO FOR THERAPEUTIC USE, LIKE AUTOLOGOUS  
15 TRANSPLANT WHERE A CHILD OR A NEAR RELATIVE NEEDS CORD  
16 BLOOD THAT'S STORED TO BE USED, WE HAVE TYPICALLY SEEN  
17 THAT IT'S THE LEGAL GUARDIANS OR PARENTS WHO HAVE THE  
18 DECISION-MAKING AUTHORITY ON THE THEORY THAT THE CORD  
19 BLOOD IS A RESOURCE THAT THE CHILD IS IN SOME SENSE  
20 ENTITLED TO HAVE. AND SO ANY DONATION OF THAT RESOURCE  
21 OR USE OF IT FOR THERAPY WOULD ORDINARILY BE A DECISION  
22 FOR THE CHILD'S LEGAL PARENTS OR GUARDIANS.

23 WHERE THE CORD BLOOD IS GOING TO BE USED FOR  
24 STEM CELL RESEARCH, AS IN BERNIE'S SCENARIO WHERE  
25 YOU'RE NOW DEVELOPING CELL LINES THAT CARRY GENETIC



1 INFORMATION THAT'S REVELATORY ABOUT THE GENETIC  
2 PARENTING, THE GENETIC PROGENITORS, I'LL SAY, YOU WOULD  
3 WANT THE PEOPLE WHOSE PRIVACY INTERESTS ARE BEING  
4 IMPLICATED TO BE THE DECISION MAKERS. AND THE LEGAL  
5 GUARDIAN OF THE CHILD WOULD BE APPROPRIATELY, AS YOU  
6 SAY, OUT OF THE MIX.

7 THE TROUBLE IS AT THE TIME YOU'RE COLLECTING  
8 THE CORD BLOOD, YOU'RE NOT SURE IF IT'S GOING TO BE ONE  
9 OR BOTH USES. SO THE PROVISION AS ORIGINALLY WRITTEN  
10 THOUGHT TO COVER ALL BASES, WE GET ALL POSSIBLE  
11 PERMISSIONS; AND IF YOU CAN'T, THEN YOU JUST DO WITHOUT  
12 THAT PARTICULAR CORD BLOOD SAMPLE. THERE OUGHT TO BE  
13 PLENTY OF THEM TO GO AROUND. I UNDERSTOOD POLITICALLY  
14 THAT THERE WAS A LOT OF CONCERN IN ADDING ANYBODY  
15 BEYOND THE WOMAN GIVING BIRTH BECAUSE OF THE ECHOES OF  
16 ABORTION DEBATES AND THE ROLE OF OTHER PEOPLE BESIDES  
17 THE PREGNANT WOMAN HERSELF, BUT THE ISSUES HERE WERE  
18 DISTINCTLY DIFFERENT, ESPECIALLY WITH REGARD TO PRIVACY  
19 CONCERNS FOR STEM CELL LINES.

20 CO-CHAIR LANSING: WHAT IF YOU DON'T KNOW THE  
21 GENETIC BASIS?

22 MS. CHARO: WELL, PRESUMABLY IF YOU DON'T  
23 KNOW WHO THE GENETIC FATHER OF THE CHILD IS, YOU WOULD  
24 NOT BE ABLE TO OFFER THIS CORD BLOOD FOR DONATION. OR  
25 IF YOU DID NOT WISH TO REVEAL THAT INFORMATION, WHICH

1 MANY PEOPLE MAY NOT WISH TO REVEAL, YOU SIMPLY WOULDN'T  
2 DONATE THIS CORD BLOOD FOR THESE RESEARCHERS.

3 CO-CHAIR LANSING: BUT YOU COULD STILL USE IT  
4 FOR THE CHILD, YOUR CHILD.

5 MS. CHARO: ABSOLUTELY. THAT'S THE POINT.  
6 IF YOU WANTED TO SIMPLY PUT IT INTO STORAGE FOR PURELY  
7 THERAPEUTIC PURPOSES FOR THE CHILD OR THE CHILD'S NEAR  
8 RELATIVES IN THE FUTURE, THAT, ALTHOUGH IT'S A  
9 DEVELOPING AREA OF LAW, GENERALLY CAN BE DONE ON THE  
10 PREGNANT WOMAN OR BIRTH MOTHER'S OWN INITIATIVE WITHOUT  
11 ADDITIONAL INVOLVEMENT FROM PEOPLE THAT ARE UNKNOWN OR  
12 UNKNOWABLE.

13 CO-CHAIR LO: ALTA, LET ME ASK YOU ANOTHER  
14 QUESTION TO FOLLOW UP SHERRY'S. IF THE WOMEN GIVING  
15 BIRTH WANTED TO DONATE THE CORD BLOOD TO A CORD BLOOD  
16 BANK THAT MIGHT BE USED BY OTHER CHILDREN RATHER THAN  
17 THEIR OWN, SHE COULD DO THAT ON HER OWN?

18 MS. CHARO: YES, SHE CAN. I'M SAYING THAT  
19 DEFINITELY, BUT THE FACT IS THIS IS AN EVOLVING AREA  
20 OF LAW, AND WE'RE STRUGGLING ACROSS THE 50 STATES TO  
21 DEVELOP COMMON RULES ABOUT THIS. AND I HAVE TO CONFESS  
22 I DON'T FEEL COMPLETELY UP TO SPEED ON THE DETAILS OF  
23 EACH OF THOSE STATE LAWS.

24 CO-CHAIR LO: IT SOUNDS LIKE THOSE ARE  
25 THERAPIES THAT ARE WELL ESTABLISHED. CORD BLOOD

1 TRANSFUSIONS --

2 MS. CHARO: IT'S USUALLY FOR BONE MARROW  
3 TRANSPLANT.

4 CO-CHAIR LO: NOW, WE'RE TALKING ABOUT  
5 CIRM-FUNDED RESEARCH. AND I GUESS ALTA RAISED THE  
6 QUESTION. DO WE WANT TO SINGLE OUT CIRM-FUNDED  
7 RESEARCH AIMED AT THE DERIVATION OF THE STEM CELL LINE  
8 AS OPPOSED TO CIRM-FUNDED RESEARCH THAT MIGHT BE USED  
9 FOR OTHER PURPOSES THAT DOESN'T IMPLICATE THE PRIVACY  
10 RIGHT OF THE GENETIC --

11 MS. CHARO: IF PEOPLE KNEW EX ANTE, THAT IS  
12 BEFOREHAND, EXACTLY WHAT THEY WERE PLANNING TO DO WITH  
13 THIS, THAT MIGHT BE ENTIRELY POSSIBLE AND WE COULD  
14 ALTER THIS SO THAT IT ONLY INCORPORATED THE PROGENITORS  
15 IN CASES IN WHICH THE CORD BLOOD'S GOING TO BE USED TO  
16 DERIVE SUSTAINABLE CELL LINES. SURE.

17 CO-CHAIR LO: JOHN WAGNER, ARE YOU ON THE  
18 PHONE?

19 DR. WAGNER: I'M STILL ON THE PHONE, EXCEPT  
20 AS YOU CAN GUESS, I CAN ONLY HEAR BITS AND PIECES.

21 CO-CHAIR LO: OKAY. I REALLY THINK YOUR  
22 INPUT HERE WOULD BE VERY USEFUL BECAUSE THIS IS YOUR  
23 SPECIALTY. SO STOP ME IF THIS IS NOT COMING THROUGH.

24 SO WE'RE TALKING ABOUT THE ISSUE OF CONSENT  
25 FOR DONATION OF CORD BLOOD OR PLACENTAL TISSUE FOR

1 CIRM-FUNDED RESEARCH. AND POINTING OUT THAT WHILE THE  
2 WOMAN UNILATERALLY CAN DONATE THAT CORD BLOOD FOR STEM  
3 CELL BANKING, EITHER FOR AUTOLOGOUS TRANSFUSION OR  
4 OTHER TRANSFUSION OR, I SUPPOSE, FOR RESEARCH NOT  
5 INVOLVING STEM CELL LINES, WE HAD IN OTHER CONTEXTS,  
6 INCLUDING OOCYTE DONATION AND SPERM DONATION, SAID THAT  
7 DERIVING A STEM CELL, A PLURIPOTENT STEM CELL LINE THAT  
8 MAY BE USED FOR TRANSPLANTATION IN HUMANS AND ANIMALS,  
9 WE WOULD KEEP THAT DNA PROPAGATING IN THE LAB FOR SOME  
10 TIME, RAISES CONCERNS ABOUT THE DONOR'S WILLINGNESS TO  
11 DO THAT.

12 THAT IN OTHER CONTEXT WE HAD SAID BOTH  
13 GENETIC PARENTS NEED TO AGREE TO HAVE THAT MATERIAL  
14 USED FOR DERIVATION OF NEW STEM CELL LINES. I GUESS  
15 SINCE YOU HAVE A LOT OF EXPERIENCE WITH CORD BLOOD  
16 BANKING AND TRANSFUSIONS, I WANT TO PARTICULARLY GET  
17 YOUR INPUT ON WHETHER, IN LIGHT OF THE PUBLIC CONCERNS,  
18 THAT SOME OF THE PUBLIC OBJECTIONS TO THAT REQUIREMENT  
19 OF CONSENT FROM BOTH PARENTS, YOUR THOUGHTS ON THIS.

20 DR. WAGNER: I THINK I UNDERSTAND THE  
21 QUESTION. I THINK THAT FROM A PRACTICALITY POINT OF  
22 VIEW, AS IT TURNS OUT, THERE'S A SIGNIFICANT PROPORTION  
23 OF FATHERS THAT AREN'T PRESENT AT THE TIME OF DELIVERY  
24 AND ARE NOT ABLE TO PROVIDE CONSENT. FOR PURPOSES OF  
25 POTENTIAL RESEARCH, REMEMBER THAT WHEN THE CORD BLOOD

1 IS BEING COLLECTED, WE DON'T KNOW IF IT'S GOING TO BE  
2 AVAILABLE FOR RESEARCH OR NOT OR WHETHER IT WILL BE  
3 STORED SPECIFICALLY FOR HEMATOPOETIC STEM CELL  
4 TRANSPLANTATION. SO UP FRONT YOU WOULD HAVE TO MAKE A  
5 GUESS THAT A PORTION OF THESE UNITS WILL BE AVAILABLE  
6 FOR RESEARCH AND OTHERS WILL NOT BE. AND I WOULD SAY  
7 PROBABLY ABOUT 50 PERCENT ARE REALLY AVAILABLE FOR  
8 RESEARCH BECAUSE THEY DON'T MEET ALL THE CRITERIA  
9 REQUIRED FOR STORAGE IN A BANK.

10 THE NEXT PART OF ALL THIS, THEN, IS THAT WE  
11 DON'T REQUIRE THE FATHER TO SIGN THE CONSENT FOR  
12 HEMATOPOIETIC STEM CELL STORAGE, BUT THERE WAS A LOT OF  
13 DEBATE IN THE IOM COMMITTEE MEETING A YEAR AND A HALF  
14 AGO (INAUDIBLE BECAUSE OF PHONE TRANSMISSION) WHETHER  
15 OR NOT YOUR (INAUDIBLE BECAUSE OF PHONE TRANSMISSION)  
16 FOR VERY SPECIFIC STEM CELL RESEARCH, THAT YOU MIGHT  
17 SAY UP FRONT I WANT TO SELECT THIS CORD BLOOD UNIT FOR  
18 STEM CELL RESEARCH. WELL, THEN, WE NEED TO GET ALL THE  
19 REQUIRED DOCUMENTS. BUT REMEMBER FOR THE MAJORITY OF  
20 CORD BLOOD BANKS OUT THERE, THEY ASK YOU IF YOU'D ALLOW  
21 THEM TO BE USED FOR RESEARCH POTENTIALLY WITH ALL THE  
22 POSSIBLE THERAPEUTIC USES THERE MIGHT BE IN THE FUTURE.

23 SO YOU HAVE TO BE ABLE TO BE TARGETING  
24 SPECIFIC BANKS, SPECIFIC PEOPLE, I THINK HAVING AN  
25 EXTRA REQUIREMENT ABOVE AND BEYOND WHAT YOU NORMALLY DO

1 FOR RESEARCH. DOES THAT HELP?

2 CO-CHAIR LO: THE LAST PART WE DIDN'T  
3 QUITE -- THE PUNCH LINE DIDN'T QUITE COME THROUGH. SO  
4 A REQUIREMENT -- I THINK WE UNDERSTAND YOU ARE SAYING  
5 THAT A REQUIREMENT OF PATERNAL CONSENT TO USE THE  
6 MATERIALS FOR STEM CELL RESEARCH IS BEYOND CONSENT  
7 THAT'S USED FOR OTHER EITHER AUTOLOGOUS BONE MARROW  
8 STORAGE OR DONATION TO A CORD BLOOD BANK OR OTHER CORD  
9 BLOOD RESEARCH. AND YOU SAID THERE MAY BE SOME  
10 LOGISTIC PROBLEMS BECAUSE THE DAD MAY NOT ALWAYS BE  
11 PRESENT IN THE DELIVERY ROOM.

12 WHAT I DIDN'T HEAR WAS THE BOTTOM LINE OF  
13 WHETHER YOU WOULD AGREE WITH OR DISAGREE WITH REQUIRING  
14 IN THE CASE OF CORD BLOOD USED FOR STEM CELL DERIVATION  
15 THE PATERNAL PROGENITOR'S CONSENT.

16 DR. WAGNER: WELL, I THINK THE ONLY WAY THAT  
17 THAT'S GOING TO WORK IS TO SPECIFICALLY ASK THE CORD  
18 BLOOD UNIT FOR STEM CELL RESEARCH. TYPICAL CORD BLOOD  
19 BANK THAT'S DOING THIS ON LARGE SCALE FOR CORD BLOOD  
20 BANKING FOR HEMATOPOETIC STEM CELL TRANSPLANT MAY NOT  
21 BE ABLE TO DO WHAT YOU'RE ASKING. SO YOU MAY NOT BE  
22 ABLE TO DO THAT RETROSPECTIVELY, BUT YOU SURELY COULD  
23 HAVE -- CIRM COULD MANDATE IT. AND YOU ARE GOING TO  
24 HAVE TO REALLY FOCUS YOUR COLLECTION SPECIFICALLY FOR  
25 RESEARCH PURPOSES, AND THAT COULD BE DONE. BUT THEN

1 YOU ARE GOING TO BE DENYING YOURSELF ACCESS TO WIDE  
2 GENETIC DIVERSITY.

3 CO-CHAIR LO: SO YOUR CONCERN IS THE  
4 LOGISTICS MAY BE FORMIDABLE, AND THERE MAY BE  
5 IMPLICATIONS FOR A NONDIVERSE DONOR POOL AS WELL.

6 DR. WAGNER: I THINK THERE'S A DOWNSIDE, IN  
7 OTHER WORDS, IF YOU'RE GOING TO HAVE THIS REQUIREMENT.  
8 BUT ON THE OTHER HAND, YOU KNOW, THERE ARE STRATEGIES  
9 FOR ALLOWING IT TO BE DONE WHERE YOU REQUIRE BOTH.  
10 IT'S NOT IMPOSSIBLE, BUT IT'S GOING TO BE RESTRICTING  
11 WHERE YOU COULD GET SUCH FOR CORD BLOOD RESEARCH.

12 CO-CHAIR LO: AND, AGAIN, JUST TO REMIND  
13 EVERYBODY OF THE ANALOGY. A SIMILAR CASE PERTAINS IN  
14 SPERM DONORS IN IVF WHERE EMBRYOS ARE THEN, AFTER THE  
15 WOMAN COMPLETES HER FERTILITY TREATMENT, DONATED FOR  
16 RESEARCH. WE REQUIRE THOSE SPERM DONORS TO GIVE  
17 CONSENT EVEN THOUGH THEY MAY NOT BE IN THE PICTURE AT  
18 ALL AFTER GIVING THEIR ORIGINAL DONATION. REALIZING  
19 THAT WOULD CUT DOWN ON THE NUMBER OF OOCYTES REMAINING  
20 AFTER IVF FOR STEM CELL DERIVATION.

21 DR. WAGNER: ONE OTHER THING, IT IS  
22 CONCEIVABLE THAT, FOR EXAMPLE, ONCE YOU'VE DERIVED AT A  
23 SPECIFIC STEM CELL LINE THAT WAS AT A SPECIFIC AGE,  
24 WEIGHT, AND HEIGHT, ONLY WAY THAT YOU CAN DO THAT IS IF  
25 YOU GO BACK TO EITHER THE NATIONAL MARROW BLOOD

1       REGISTRY OR THE CORD BLOOD REGISTRY AND SAY I WANT TO  
2       HAVE THIS AGE, WEIGHT, AND HEIGHT SPECIFICALLY COMMON  
3       IN, FOR EXAMPLE, (INAUDIBLE) POPULATION. I'M MAKING  
4       THAT IF THAT WERE THE CASE. WELL, THEN, IF YOU WANT TO  
5       GO BACK TO THEM AND SAY I WANT THAT AGE, WEIGHT, AND  
6       HEIGHT, AND I CAN ENVISION WHERE YOU MIGHT WANT TO DO  
7       THAT, AND YOU MIGHT THEN FIND THE CORD BLOOD UNIT OR  
8       UNITS THAT HAVE THE DESIRED AGE, WEIGHT, AND HEIGHT,  
9       AND YOU DON'T HAVE THAT PARENTAL PERMISSION OF BOTH  
10      SIDES. SO THAT'S THE DOWNSIDE.

11               CO-CHAIR LO: IS IT POSSIBLE TO GO BACK, IF  
12      THE DAD'S IN THE DELIVERY ROOM, BUT THERE'S AN ONGOING  
13      RELATIONSHIP, COULD YOU THEN STILL GO BACK THROUGH THE  
14      MOTHER TO RECONTACT THE GENETIC FATHER AND SAY WE NOW  
15      WOULD LIKE YOUR CONSENT TO USE THIS CORD BLOOD FOR THIS  
16      SPECIFIC RESEARCH PURPOSE? OBVIOUSLY THERE'S SOME  
17      INEFFICIENCY THERE, BUT IT STRIKES ME IT WOULDN'T  
18      COMPLETELY SHUT THE DOOR TO GETTING CONSENT AFTER THE  
19      ORIGINAL DONATION TO THE CORD BLOOD BANK.

20               DR. WAGNER: I PRESUME IT IS POSSIBLE TO GO  
21      BACK. I KNOW THAT MANY OF THE BANKS DO KEEP THAT  
22      LINKAGE FOR A VARIETY OF REASONS, BUT MAYBE  
23      HOSPITALS -- WE HAVE TO TALK TO THE BANKS THEMSELVES TO  
24      KNOW HOW LIKELY THAT WOULD SUCCEED OR NOT. ALSO, AS I  
25      THINK SOMEONE WAS BRINGING UP BEFORE, THERE'S ALWAYS



1 THAT QUESTION ABOUT THE ACTUAL PATERNITY ANYWAY.

2 CO-CHAIR LO: OKAY. ALL RIGHT.

3 DR. PRIETO: IT OCCURRED TO ME THAT SOME OF  
4 THIS MAY BE SORT OF A RECORDKEEPING ISSUE, THAT IF WE  
5 DECIDED TO IMPOSE THIS HIGHER LEVEL OF CONSENT FOR THIS  
6 SITUATION FOR RESEARCH, THAT THAT CONSENT COULD BE  
7 REQUESTED UP FRONT AND THOSE UNITS WHERE THAT HIGHER  
8 LEVEL -- CONSENT FROM BOTH PARENTS WAS AVAILABLE WOULD  
9 IN THE FUTURE BE ELIGIBLE FOR SUCH RESEARCH, AND OTHER  
10 UNITS WOULD ONLY BE AVAILABLE THERAPEUTIC PURPOSES. IF  
11 YOU HAVE RECORDS OF WHAT LEVEL OF CONSENT WAS OBTAINED  
12 UP FRONT, THEN YOU COULD DETERMINE THAT AT WHATEVER  
13 POINT.

14 DR. WAGNER: I THINK IT'S POSSIBLE TO DO, BUT  
15 REMEMBER (UNINTELLIGIBLE) WHICH YOU HAVE ACCESS TO IS  
16 NOT THE STANDARD PRACTICE BY CORD BANKS. REMEMBER THIS  
17 IS NOT THEIR PRIMARY GOAL. THE PRIMARY GOAL IS TO HAVE  
18 A HEMATOPOETIC STEM CELL SOURCE.

19 MS. CHARO: I JUST WANT TO NOTE THAT IF WE  
20 ARE IN A SITUATION IN WHICH THE PATERNAL PROGENITOR IS  
21 UNIDENTIFIED, WHETHER BY CHOICE OR BY IMPOSSIBILITY,  
22 THAT AT THAT POINT CORD BLOOD DONATION ON THE WOMAN'S  
23 OWN INITIATIVE DOES NOT IMPLICATE THE PATERNAL PRIVACY  
24 BECAUSE UNLESS YOU CAN LINK THE GENETIC INFORMATION TO  
25 AN IDENTIFIABLE PERSON, THERE'S NO PRIVACY ISSUE. SO

1 IF OUR MAIN CONCERN HERE IS PROTECTING THE PRIVACY OF  
2 THE PROGENITORS, WE WOULD BE FINE SAYING ONLY THAT THE  
3 DONATION CAN ONLY PROCEED WITH THE CONSENT OF THE BIRTH  
4 MOTHER AND MAY NOT PROCEED OVER THE KNOWN OBJECTION OF  
5 ANY PATERNAL PROGENITOR. RIGHT.

6 BUT IF THE CONCERN IS THAT PEOPLE SHOULD HAVE  
7 CONTROL OVER WHETHER OR NOT THEIR TISSUES HAVE BEEN  
8 DRAFTED INTO THE SERVICE OF RESEARCH, THEN THE ABSENCE  
9 OF SOME KIND OF DECISION FROM THAT PROGENITOR IS STILL  
10 PROBLEMATIC. NOW, WE DO, IN GENERAL, ALLOW RESEARCH TO  
11 GO FORWARD WITHOUT GETTING CONSENT FROM PEOPLE WHERE  
12 IT'S MINIMAL RISK AND CONSENT IS CONSIDERED TO BE  
13 IMPRACTICAL. THAT IS THE STANDARD FEDERAL APPROACH FOR  
14 HUMAN SUBJECTS RESEARCH. SO THERE IS PRECEDENT FOR IT,  
15 BUT IT'S PREMISED ON THE IDEA THAT IT'S IMPRACTICAL TO  
16 GET THE CONSENT.

17 EVEN FOR MINIMAL RISK WORK, RIGHT, WE  
18 GENERALLY SAY CONSENT IS REQUIRED IF IT'S FEASIBLE.  
19 I'D LIKE US TO AT LEAST CLARIFY WHAT WE'RE TRYING TO  
20 PROTECT BY ASKING FOR THE PATERNAL PROGENITOR'S  
21 CONSENT. IS IT PRIVACY, THE PRIVILEGE TO REFUSE  
22 PARTICIPATION IN RESEARCH, OR BOTH? AND SECOND,  
23 WHETHER EVEN IF IT'S BOTH, IF WE THINK THIS IS A  
24 SITUATION IN WHICH SUCH CONSENT COULD BE WAIVED, AND  
25 THAT WOULD LEAVE WITH US A PROVISION PRESUMABLY THAT

1 SAYS THAT THE DONATION CAN BE MADE ON THE WOMAN'S OWN  
2 INITIATIVE. I WOULD SUGGEST THAT IF THERE'S A KNOWN  
3 OBJECTION, THAT IT SHOULD BE HONORED BY THE MALE  
4 PROGENITOR. AND THAT IN OTHER CIRCUMSTANCES, WE CAN GO  
5 FORWARD WITHOUT CONTACT.

6 I JUST WANT US TO BE CLEAR ABOUT WHAT WE'RE  
7 TRYING TO ACCOMPLISH.

8 DR. PRIETO: I THINK THAT THAT'S A GOOD POINT  
9 BECAUSE I THINK THAT ABSENT THE KNOWN OBJECTION, ONE OF  
10 THE PRINCIPLES YOU HAVE TO GO BACK TO IS IS THERE ANY  
11 POTENTIAL HARM. ARE YOU HARMING THIS PERSON IN ANY  
12 WAY? AND I CAN'T SEE THAT.

13 MS. CHARO: KEEP IN MIND, THOUGH, THAT IN THE  
14 AREA OF DONATING EMBRYOS THAT WERE CREATED WITH  
15 ANONYMOUS DONOR SPERM, AS BERNIE WAS JUST POINTING OUT,  
16 THERE WE FOLLOWED THE NAS GUIDELINES, WHICH ADMITTEDLY  
17 WERE HOTLY CONTESTED, IN RECOMMENDING THAT EMBRYOS NOT  
18 BE USED UNTIL ALL OF THE GENETIC DONORS COULD BE  
19 IDENTIFIED AND GIVE CONSENT ON THE THEORY THAT IT  
20 DIDN'T MATTER IF THEY WERE ACTUALLY HARMED, BUT  
21 SOMEBODY WHOSE PARTICIPATION AND ACTIVITY WAS FOR  
22 REPRODUCTIVE PURPOSES OUGHT HAVE THEIR RESULTING  
23 MATERIALS, RESULTING EMBRYOS, CORD BLOOD DRAFTED INTO  
24 RESEARCH WITHOUT THEIR KNOWLEDGE AND CONSENT BECAUSE IT  
25 WASN'T PART OF THE ORIGINAL INTENT IN THE ACTIVITY.

1 DR. PRIETO: ISN'T THIS IN SOME WAYS  
2 ANALOGOUS TO WHAT WE WERE TALKING ABOUT EARLIER WITH  
3 OOCYTE DONORS? ANALOGOUS TO THE SITUATION WE WERE  
4 DISCUSSING EARLIER IN THAT IF THEY ARE OFFERED THE  
5 OPTION TO OBJECT, IF THEY ARE INVOLVED AND IDENTIFIABLE  
6 AND CHOOSE TO BE IDENTIFIED AND ARE OFFERED THE OPTION  
7 TO OBJECT, THEN HAVEN'T YOU MET YOUR OBLIGATIONS TO  
8 THAT PERSON? NOT ONLY HAVE YOU ELIMINATED HARM, WHICH  
9 IS OBVIOUSLY THE FIRST PRINCIPLE, BUT YOU ARE ALSO  
10 ALLOWING OBJECTION ON WHATEVER PRINCIPLES THEY FOLLOW.

11 MS. CHARO: IT IS A LITTLE BIT -- IT'S A  
12 LITTLE BIT LIKE THE TREE THAT FALLS IN THE FOREST THAT  
13 NOBODY HEARS. I COMPLETELY ADMIT TO YOU, RIGHT. SO  
14 YOU'VE GOT TWO SITUATIONS, RIGHT, THAT ARE SOMEWHAT  
15 ECHOING EACH OTHER. YOU'VE GOT A SPERM DONOR FROM 2001  
16 WHO DONATED SPERM -- DIDN'T DONATE, PROBABLY SOLD, TO  
17 BE MORE ACCURATE -- SPERM IN ORDER TO MAKE SOME MONEY  
18 AND UNDERSTOOD THAT THE OUTCOME WAS GOING TO BE THAT  
19 SOME WOMEN WILL GET PREGNANT AND THERE WILL BE  
20 OFFSPRING IN THE WORLD NEVER KNOWS THAT, IN FACT, SOME  
21 OF THE RESULTING EMBRYOS WERE DIVERTED TO RESEARCH  
22 PURPOSES UPON CONSENT FROM THE CUSTODIANS OF THOSE  
23 EMBRYOS. SO DOESN'T KNOW THAT, IN FACT, HIS  
24 INTERACTION WITH A SPERM DONATION PROCESS, IN FACT,  
25 RESULTED IN EMBRYOS THAT WERE DESTROYED AND EMBRYONIC

1       STEM CELL RESEARCH THAT OCCURRED.   DOESN'T KNOW IT.

2                   IS THAT PERSON IN ANY WAY -- HAS THAT PERSON  
3       BEEN WRONGED IN ANY SENSE THAT WE WANT TO ACCOUNT FOR,  
4       RIGHT?   AND THAT WOULD BE SIMILAR HERE WITH THIS  
5       PROGENITOR WHO HAD SEXUAL RELATIONS WITH SOMEBODY, MAY  
6       OR MAY NOT KNOW THAT CONCEPTION OCCURRED, MAY OR MAY  
7       NOT KNOW THAT A CHILD WAS BORN, MAY OR MAY NOT KNOW  
8       THAT CORD BLOOD IS AVAILABLE FOR DONATION, BUT  
9       CERTAINLY NEVER CONTEMPLATED AT THE TIME OF THE INITIAL  
10      CONTACT WITH THIS WOMAN THAT ONE OF THE RESULTS MIGHT  
11      BE THAT HE IS NOW PART OF A RESEARCH ENDEAVOR.

12                   DR. PRIETO:   HAVE YOU MET THE REQUIREMENTS OF  
13      THAT PERSON OR YOUR OBLIGATIONS TO THAT PERSON IF YOU  
14      OFFER THE OPTION TO BE HEARD?

15                   MS. CHARO:   BUT YOU MAY NOT KNOW THAT PERSON.

16                   DR. PRIETO:   YOU'D LET IT BE KNOWN THAT -- IF  
17      THE PERSON IS A DONOR, THAT CAN BE PART OF THE CONSENT  
18      PROCESS, THAT RESEARCH IS ONE POTENTIAL OUTCOME OF THIS  
19      AND YOU MAY BE HEARD, IF YOU WISH, IN THE FUTURE ON  
20      THOSE ISSUES IF YOU CHOOSE TO REMAIN AVAILABLE TO THE  
21      PERSON WHO HAS NO IDEA AND CHOOSES NOT TO BE INVOLVED  
22      WITH THE PARTNER WHO THEY'VE GOTTEN PREGNANT.

23                   MS. CHARO:   THAT'S EXACTLY THE POINT.   THAT'S  
24      EXACTLY THE ISSUE, AND I REALLY DO THINK IT'S QUITE  
25      SIMILAR TO THE ONE ABOUT THE SPERM DONOR, RIGHT.

1 THAT'S EXACTLY THE POINT WHERE SOMEBODY IS UNKNOWN AND  
2 UNKNOWABLE, RIGHT.

3 DR. PRIETO: BUT --

4 MS. CHARO: AND ON TOP OF EVERYTHING ELSE  
5 PROBABLY WILL NEVER KNOW EVEN WHAT HAPPENED. DO WE  
6 NONETHELESS WANT TO SAY WE SHOULDN'T DO THIS? IT'S A  
7 KIND OF --

8 DR. PRIETO: I THINK THE SPERM DONOR IS NOT  
9 UNKNOWABLE.

10 CO-CHAIR LO: LET'S GET SOME MORE PEOPLE.

11 CO-CHAIR LANSING: I THINK IT'S A REALLY  
12 INTERESTING ISSUE. AND, AGAIN, I COME BACK TO WHAT  
13 WE'RE STARTING AS OUR RULES AND ERRING ON THE SIDE OF  
14 BEING EXTREMELY CONSERVATIVE AND TRYING NOT TO LEAVE  
15 OURSELVES OPEN TO ANY POSSIBLE LOOPHOLES. SO I'LL JUST  
16 TAKE THE SPERM DONOR. I ASSUME THEY KNOW THAT IT'S FOR  
17 REPRODUCTIVE RIGHTS. THAT'S WHAT THEY'RE DOING. THEY  
18 HAVE NO IDEA WHAT ELSE IS GOING TO HAPPEN TO IT; AND IF  
19 YOU LEAVE YOURSELF OPEN TO SOMEHOW OR ANOTHER THEM  
20 FINDING OUT THAT IT WAS USED FOR SOMETHING ELSE --

21 DR. PRIETO: IN ORDER TO USE THEIR MATERIAL,  
22 I THINK YOU HAVE TO PUT THAT OPTION FORWARD AS PART OF  
23 THEIR CONSENT PROCESS.

24 MS. CHARO: BUT THEY'RE NOT PRESENT.

25 DR. PRIETO: WHEN THEY ARE SPERM DONORS --

1 CO-CHAIR LO: SPERM DONORS AT LEAST HAVE A  
2 CHANCE TO GET THEIR CONSENT.

3 DR. PRIETO: THIS MAY BE USED FOR RESEARCH  
4 AND YOU HAVE THE -- THEN IT SHOULD BE PART OF THE  
5 CONSENT PROCESS.

6 MS. CHARO: THE NEXT TIME I HAVE SEX, I'LL  
7 ASK MY MALE COMPANION WHETHER OR NOT HE'S GIVING  
8 PROSPECTIVE CONSENT FOR CORD BLOOD DONATION.

9 CO-CHAIR LANSING: THAT'S, I THINK, THE  
10 PROBLEM. DO YOU KNOW? YOU ALSO HAVE THE PROBLEM  
11 THAT -- THAT'S A GREAT REMARK.

12 (OVERLAPPING SPEAKERS.)

13 CO-CHAIR LANSING: I THINK THAT, YOU KNOW,  
14 YOU MIGHT NOT KNOW WHO IT IS. I JUST -- I'M ALWAYS  
15 GOING TO BE EXTREME, AND I'M ALWAYS TRYING TO PROTECT  
16 US FROM THE EXTREME CASE THAT COULD SLOW US UP. AND SO  
17 I'M SAYING TO MYSELF, OKAY, SO YOU DIDN'T KNOW WHO THE  
18 FATHER WAS, AND SOMEHOW OR ANOTHER 20 YEARS FROM NOW  
19 THEY FIGURE IT OUT, AND HE SAYS, "WAIT A MINUTE. I  
20 DIDN'T GIVE YOU THE RIGHT TO DO THAT." SO WHY NOT  
21 CERTAINLY IN OUR FIRST GO-ROUND ERR ON THE SIDE OF  
22 BEING CONSERVATIVE?

23 I REALLY DO THINK -- THE THING THAT I WAS  
24 MOST CONCERNED ABOUT IS, OKAY, I'M THE PROSPECTIVE  
25 MOTHER, I DON'T KNOW WHO THE FATHER IS, I WANT TO HELP

1 MY CHILD. AND THAT'S PROTECTED. THAT'S WHERE I'M  
2 REALLY CONCERNED ABOUT. I WANT TO HELP MY IMMEDIATE  
3 OFFSPRING, AND I DON'T WANT TO BE STOPPED BY NOT  
4 KNOWING WHO THE FATHER IS, WHATEVER.

5 BEYOND THAT, I'M JUST HOPING THAT THERE'S  
6 GOING TO BE SO MUCH POTENTIAL FOR DONATIONS, THAT WE'RE  
7 NOT GOING TO NEED TO WORRY ABOUT THIS AT THIS TIME. I  
8 JUST THINK ERRING ON THE SIDE OF THE CONSERVATIVE  
9 INITIALLY WILL PROTECT US FROM ANY POTENTIAL LOOPHOLES  
10 OR WHATEVER.

11 DR. OLDEN: HER POSITION IS EXACTLY THE  
12 POSITION THAT I TAKE AS WELL. I'M VERY COMFORTABLE  
13 WITH THAT, BUT I'M UNCOMFORTABLE WITH THE OTHER.

14 CO-CHAIR LO: LET ME ALSO SAY SOME OTHER  
15 THINGS. I THINK THIS HAS BEEN A VERY IMPORTANT AND  
16 INTERESTING DISCUSSION. I THINK ALTA VERY WELL RAISED  
17 SOME ISSUES.

18 IT STRIKES ME THERE ARE A COUPLE ARGUMENTS  
19 WE'D WANT TO MAKE FOR HAVING CONSENT FROM THE GENETIC  
20 FATHER. ONE IS THAT IMPLIED CONSENT FOR REPRODUCTION  
21 IS DIFFERENT THAN CONSENT FOR ANY RESEARCH, AND  
22 SPECIFICALLY STEM CELL DERIVATION RESEARCH. IT STRIKES  
23 ME THAT THIS IS NOT JUST ANY RESEARCH, BUT RESEARCH  
24 ABOUT WHICH PEOPLE, EVEN MORE THAN OTHER TYPES OF  
25 RESEARCH, HAVE STRONG INDIVIDUAL PREFERENCES. AND THE



1 IDEA IS THAT WE SHOULD TRY AND HONOR THOSE -- WE SHOULD  
2 ONLY USE DONORS FOR EXPERIMENTS WE KNOW.

3 I'M REMINDED OF THE TIMES WHERE PEOPLE'S  
4 STUFF GOT USED FOR RESEARCH WITHOUT THEIR KNOWLEDGE OR  
5 CONSENT. THE HENRIETTA LACKS CELL LINE AND THE MOORE  
6 SPLEEN LINE. AND PEOPLE GET REALLY UPSET WHEN THEY  
7 SAY, "I THOUGHT YOU WERE GOING TO DO THIS WITH IT, AND  
8 NOW IT TURNS OUT YOU'RE DOING SOMETHING ELSE." SO  
9 THAT'S ONE THING.

10 I THINK THE OTHER ANALOGY IS TRANSPLANTATION.  
11 WE DON'T TAKE MATERIALS FOR TRANSPLANTATION FROM PEOPLE  
12 WITHOUT THEIR CONSENT OR THEIR FAMILY'S CONSENT IN THE  
13 CASE OF DISEASED DONORS. AND AGAIN, IT'S BECAUSE, EVEN  
14 THOUGH IT'S THOUGHT TO BE A GOOD THING OR BENEFICIAL  
15 THING, PEOPLE HAVE DIFFERENT FEELINGS ABOUT THAT. IF  
16 THE ULTIMATE GOAL OF STEM CELL RESEARCH IS  
17 TRANSPLANTATION, YOU KNOW, YOU ARE GOING TO HAVE CELL  
18 LINES BEING TRANSPLANTED WHERE, FIRST OF ALL, YOU DON'T  
19 HAVE CONSENT FOR THAT.

20 AND I ALSO HAVE CONCERNS WITH THE UNKNOWN  
21 PARENTS, WHETHER YOU'RE GOING TO USE THOSE LINES FOR  
22 TRANSPLANTATION GIVEN THE UNKNOWN SAFETY FACTOR IN  
23 TERMS OF MEDICAL HISTORY AND SCREENING.

24 SO I JUST THINK THAT THERE ARE A LOT OF  
25 REASONS IN ADDITION TO THE ONES THAT SHERRY AND KEN

1 OLDEN LAID OUT FOR AT THIS POINT IN TIME, AT LEAST,  
2 REQUIRING CONSENT FROM THE GENETIC FATHER TO HAVE  
3 DONATION OF MATERIALS FOR CIRM-FUNDED STEM CELL  
4 DERIVATION RESEARCH. I THINK FOR OTHER TYPES OF  
5 RESEARCH, AND CERTAINLY FOR CLINICAL STORAGE, I'M  
6 COMFORTABLE WITH THE BIRTH MOTHER GIVING CONSENT.

7 BY THE WAY -- WELL, I'M GOING TO STOP THERE.  
8 IT GET'S MORE COMPLICATED WHEN OOCYTE DONORS ARE  
9 DIFFERENT FROM THE BIRTH MOTHER IN TERMS OF NEEDING HER  
10 CONSENT. ANY OTHER COMMENTS?

11 DR. TAYLOR: WITH SOME RELUCTANCE, I RAISE  
12 THIS ELEPHANT IN THE ROOM A LITTLE BIT ON THIS ONE, AND  
13 THAT'S GESTATIONAL AGE. AND REALLY CORD BLOOD AND  
14 PLACENTAL FETAL TISSUE IS SOMETHING THAT COULD BE USED  
15 AS A SOURCE OF THESE SAMPLES AT A TIME WHEN OBTAINED AT  
16 AN EARLIER GESTATIONAL PERIOD WHERE PRECEDENT EXISTS TO  
17 NOT HAVE CONSENT ACROSS THE BOARD. SO, YOU KNOW, I  
18 THINK ACTUALLY IN SOME WAYS THE LANGUAGE THAT YOU ARE  
19 PROPOSING, BERNIE, GETS US AWAY FROM THAT PARTICULAR  
20 ISSUE, BUT I THINK IT'S GOING TO BE A HARD ONE TO  
21 COMPLETELY IGNORE. AND IT'S GOT TO BE THE MOST  
22 SENSITIVE ISSUE WE CAN POSSIBLY DISCUSS HERE  
23 PRESUMABLY.

24 SO I'M WONDERING WHETHER WE CAN SORT OF  
25 RESOLVE THAT IN SOME WAY OR AVOID STRUGGLING WITH THAT

1 OR SHOULD THINK ABOUT LANGUAGE THAT WOULD STILL PROTECT  
2 THAT RIGHT OF THE WOMAN'S MAKING DECISIONS ABOUT  
3 EARLIER PREGNANCY TERMINATION.

4 CO-CHAIR LO: WELL, LET'S TRY AND DISTINGUISH  
5 THE CORD BLOOD AT DELIVERY, DONATION OF THAT PLACENTA  
6 FROM FETAL TISSUE, WHICH I AGREE GETS EVEN MURKIER.

7 MS. CHARO: YOU KNOW, ROB'S POINT, AND I  
8 UNDERSTOOD THAT THAT IS EXACTLY THE ELEPHANT IN THE  
9 ROOM. EVERYBODY IS CONCERNED ABOUT THE WAY THIS ECHOES  
10 WITH THE ABORTION DEBATES. BUT IT HIGHLIGHTS THAT  
11 PERHAPS WE'RE APPROACHING THIS LINGUISTICALLY THE WRONG  
12 WAY, AND WE MIGHT BE ABLE TO WRITE OUR WAY OUT OF IT.  
13 INSTEAD OF FOCUSING, AS WE DO NOW, ON CIRM-FUNDED  
14 RESEARCH INVOLVING THE DONATION OF CORD, CORD BLOOD, OR  
15 PLACENTA, MAYBE WE SHOULD BE FOCUSING ON CIRM-FUNDED  
16 RESEARCH THAT USES CORD BLOOD OR PLACENTA AND SIMPLY  
17 SAY THAT WE WILL ONLY FINANCE RESEARCH THAT USES CORD  
18 BLOOD AND PLACENTA WHERE BOTH PROGENITORS ARE KNOWN AND  
19 HAVE GIVEN CONSENT.

20 THAT THEN SAYS NOTHING ABOUT THE COLLECTION  
21 PROCESS. IT SAYS NOTHING ABOUT TO DO WHAT, WHEN,  
22 WHERE, WHY. IT JUST SAYS WHAT MATERIALS YOU MAY OR MAY  
23 NOT USE IN CIRM-FUNDED RESEARCH AND PERHAPS MORE  
24 CLEARLY SEPARATES THE TWO AREAS.

25 CO-CHAIR LO: I THINK THAT'S USEFUL.

1 DR. TAYLOR: THAT COVERS EVERYTHING.

2 CO-CHAIR LO: ANY OTHER COMMENTS, THOUGHTS?  
3 THOSE WHO ARE ON THE PHONE.

4 DR. WAGNER: THIS IS JOHN. I WANTED TO MAKE  
5 ANOTHER COMMENT. FIRST OFF, WE CAN'T FORGET THAT THE  
6 REAL DONOR IS THE BABY. IT'S NOT THE MOTHER OR THE  
7 FATHER. WE HAVE NO GENETIC INFORMATION ON THE FATHER  
8 ANYWAY. SO NOTHING WILL BE PASSING THROUGH BECAUSE  
9 NONE OF THE FATHER'S GENETIC INFORMATION WAS THERE.

10 SECONDLY, REMEMBER THAT ALSO THE CORD BLOOD  
11 BANKS ARE NOW APPROACHING THEIR 13TH YEAR. ALSO, THE  
12 OTHER ISSUE IS ONE THAT'S MAYBE MORE COMPLEX. WON'T BE  
13 LONG BEFORE THE CORD BLOOD BABY HIMSELF WILL BECOME 18  
14 YEARS OLD, SO THERE'S ANOTHER COMPLICATING FACTOR IN  
15 THERE IF PEOPLE WANT TO GO DOWN THAT ROAD.

16 I THINK IT'S IMPORTANT THAT WE TRY TO GO BACK  
17 AND CONSIDER THE POSSIBILITY OF RECONTACTING FAMILIES.  
18 I THINK THAT'S A REASONABLE APPROACH TO CONSIDER, BUT  
19 KNOW THAT THERE'S SOME PROBLEMS TOO WITH THAT. AND  
20 THAT IS THAT IN ADDITION TO NOT BEING ALWAYS ABLE TO  
21 CONTACT THE FATHER, WHO'S GOING TO ACTUALLY MAKE THE  
22 CONTACT? IT WON'T BE THE RESEARCHER. THE RESEARCHER  
23 WON'T BE GIVEN ACCESS TO DIRECT CONTACT. IT WILL ONLY  
24 BE THROUGH THE BANK. AND, THEREFORE, WHO'S GOING TO  
25 EDUCATE THE PEOPLE AT THE BANK TO THEN EXPLAIN WHAT

1       STEM CELL RESEARCH IS? IT'S NOT SO STRAIGHTFORWARD AND  
2       HOW THAT WILL EVEN BE ACCOMPLISHED SHOULD EVEN THAT BE  
3       REQUIRED.

4                   CO-CHAIR LO: OTHER COMMENTS? MEMBERS OF THE  
5       PUBLIC, ANY COMMENTS? YES, PLEASE.

6                   MS. COEYTAUX: THANK YOU. I'M FRANCINE  
7       COEYTAUX FROM THE PRO-CHOICE ALLIANCE. I WOULD REALLY  
8       URGE YOU TO REALLY SERIOUSLY CONSIDER THE CANADIAN  
9       LANGUAGE. I THINK IT RESOLVES A LOT OF THE QUESTIONS  
10      THAT I THINK YOU'RE DEALING WITH, AND I THINK IT GOES  
11      STRAIGHT TO SOMETHING MS. LANSING SAID A NUMBER OF  
12      TIMES. IT'S TAKING THE WOMAN, GIVING HER THE  
13      RESPONSIBILITY OF RECOGNIZING THAT, YOU KNOW, SHE'S THE  
14      ONE WHO KNOWS WHO THE FATHER IS OR DOESN'T KNOW WHO THE  
15      FATHER IS. AND UNLESS WE'RE THINKING, AS WAS JUST  
16      MENTIONED, OF ACTUALLY GENETICALLY TYPING EVERYBODY TO  
17      KNOW WHO THE FATHER AND THE MOTHER IS, REALLY WHAT  
18      WE'RE TALKING ABOUT IS DELIVERY. THERE'S A MOTHER  
19      THERE AND THERE MAY BE ANOTHER PARENT WHO'S COMMITTED  
20      TO PARENTING, AS WAS MENTIONED IN TERMS OF THE RECORDS.  
21      THESE ARE PEOPLE WHO ARE GOING THROUGH PREGNANCY. WE  
22      KNOW WHO THEY ARE IN ADVANCE. WE COULD FIND OUT IN  
23      ADVANCE WHETHER OR NOT THERE ARE TWO PEOPLE INVOLVED OR  
24      ONE PERSON INVOLVED.

25                   AND ONCE YOU GET THE PERMISSION FROM BOTH,

1 YOU'RE REALLY OFF THE HOOK. AND, FRANKLY,  
2 EPIDEMIOLOGICALLY, MOST OF THE PEOPLE ARE GOING TO BE  
3 IN THAT CATEGORY. SO BY BEING STRINGENT AND HAVING  
4 REALLY A CONSERVATIVE DECISION TO ONLY ACCEPT IF YOU  
5 HAVE BOTH PARENTS OR ONLY ONE, IF THERE'S ONLY ONE  
6 PARENT. IF IT'S A SINGLE MOTHER WHO'S SAYING I DON'T  
7 HAVE ANOTHER PARENT RESPONSIBLE FOR THIS, YOU HAVE  
8 GOTTEN ALL THAT YOU NEED, AND YOU CAN MOVE AHEAD. SO I  
9 THINK THERE IS A REASON WHY IT WAS STATED THAT WAY.  
10 AND I THINK THEY PURPOSELY SKIRTED THE ISSUE WHETHER IT  
11 WAS GENETIC BIRTH OR NOT.

12 I THINK THAT THE ISSUE, GETTING BACK TO WHAT  
13 DR. CHARO SAID ABOUT WHAT IS IT YOU'RE TRYING TO  
14 PROTECT, IF YOU'VE GOTTEN CONSENT FROM BOTH OR ONLY  
15 PARENT, YOU HAVE WILL ACCOMPLISHED WHAT YOU NEED.

16 MS. PASTORE: I'M CLARE PASTORE FROM THE  
17 AMERICAN CIVIL LIBERTIES UNION. I SUBMITTED WRITTEN  
18 COMMENTS WHICH ARE IN THE PACKET UP THERE, AND I'M A  
19 LITTLE CONFUSED BY THE NUMBERING OF THIS SECTION  
20 BECAUSE MY COMMENTS ARE ON THE PROPOSED PATERNAL OR  
21 PROGENITOR CONSENT TO DONATION OF CORD, CORD BLOOD, OR  
22 PLACENTA, WHICH WAS NUMBERED AT 100100. THIS IS 1008.

23 MR. LOMAX: JUST A CLARIFICATION, THAT WAS  
24 THE -- PRIOR TO OUR SUBMISSION TO THE OFFICE OF  
25 ADMINISTRATIVE LAW, WE HAD A SLIGHTLY DIFFERENT

1 NUMBERING SCHEME, AND UNFORTUNATELY THAT WASN'T UPDATED  
2 TO REFLECT IN THIS COMMENT. SO IT'S JUST A FAILURE TO  
3 UPDATE IN ACCORDANCE. I THINK THIS IS THE ONLY SECTION  
4 WHERE THIS OCCURS.

5 MS. PASTORE: THAT'S WHAT I UNDERSTOOD, THAT  
6 THIS SECTION, HOWEVER NUMBERED, IS THE ONE THAT I  
7 INTENDED TO COMMENT. WE'RE ALL DISCUSSING THE SAME  
8 SECTION.

9 MR. LOMAX: IT IS. WE ARE DISCUSSING THE  
10 SECTION WHICH YOU COMMENTED ON, YES.

11 MS. PASTORE: I WANT TO JUST URGE WHAT I  
12 SUGGESTED IN MY COMMENTS, THAT YOU NOT GO DOWN THE ROAD  
13 OF INTRODUCING NEW TERMS THAT DON'T EXIST IN CALIFORNIA  
14 LAW AND WHICH ARE CERTAIN TO LEAD TO LITIGATION. THERE  
15 IS NO SUCH THING AS A PROGENITOR IN CALIFORNIA LAW. I  
16 DID AN ELECTRONIC SEARCH THE OTHER NIGHT FOR THAT TERM,  
17 AND THE ONLY PLACE IT TURNS UP IS IN THE CONSTITUTIONAL  
18 PROVISIONS ABOUT CIRM DEFINING PROGENITOR STEM CELLS,  
19 BUT IT DOESN'T EXIST AS AN IDENTIFIER OF A PARENT, AN  
20 INTENDED PARENT, UNINTENDED PARENT, GUARDIAN, OR ANY  
21 SUCH THING. SO I URGE YOU NOT TO ADOPT LANGUAGE LIKE  
22 THAT WHICH WILL THEN NEED TO BE LITIGATED AND DEFINED  
23 BY THE COURTS.

24 LIKewise, THERE IS NO SUCH THING IN  
25 CALIFORNIA LAW AS A PARENT OR LEGAL GUARDIAN OF A

1 PLACENTA OR OF CORD BLOOD OR UMBILICAL CORD. THAT DOES  
2 NOT EXIST. SO THE ACLU URGES YOU TO FOLLOW THE MODEL  
3 THE CORD BLOOD BANKS USE, WHICH IS TO OBTAIN CONSENT  
4 FROM THE WOMAN.

5 THE PROBLEM WITH THE CANADIAN MODEL, AS WE  
6 SEE IT, IS THAT, ONCE AGAIN, YOU'RE INTRODUCING A VERY  
7 AMBIGUOUS TERM, TWO PEOPLE COMMITTED TO PARENTING. WE  
8 DON'T HAVE TO THINK LONG TO IMAGINE THE LITIGATION FROM  
9 THE PERSON WHO COMES IN AND SAYS I DIDN'T HAPPEN TO BE  
10 THERE THAT DAY AND SHE SAID I WASN'T COMMITTED TO  
11 PARENTING, BUT REALLY I WAS, YOU'RE OPENING A PANDORA'S  
12 BOX WITHOUT NEED.

13 IT'S CLEAR BEYOND CLARITY IN CALIFORNIA LAW  
14 THAT THE WOMAN NEED NOT SEEK ANYONE'S PERMISSION TO  
15 CONTINUE THE PREGNANCY OR TERMINATE A PREGNANCY. AND  
16 TO INTRODUCE A HEIGHTENED CONSENT REQUIREMENT FOR THIS  
17 TYPE OF DONATION IS INCONSISTENT WITH HER EXERCISE OF  
18 THOSE RIGHTS. SO WE URGE YOU TO HAVE THE CONSENT  
19 REQUIREMENT GO TO THE WOMAN ALONE AND NOT TO ANY OTHER  
20 PERSONS WHO MAY THEN HAVE TO LITIGATE OVER THEIR  
21 APPROPRIATE ROLE.

22 IN ADDITION, THINK ABOUT THE PROBLEMS OF  
23 PROOF. THE PERSON WHO'S THE HUSBAND WHO TURNS OUT NOT  
24 TO BE THE PROGENITOR, WHATEVER THAT IS, THE PERSON WHO  
25 DIDN'T -- THE MOTHER THOUGHT THEY WERE AND THEY



1 WEREN'T. YOU'RE LEADING TO LOTS OF LITIGATION ABOUT  
2 PATERNITY OVER AN ISSUE THAT IS UNNECESSARY.

3 IN A SENSE, AS YOU SET UP A REGULATORY  
4 REGIME, YOU ARE SETTING UP THE EXPECTATIONS OF  
5 PARTICIPANTS IN VARIOUS ACTIVITIES. JUST AS WE KNOW  
6 NOW THAT THE REGIME IS IF YOU ARE A MAN AND YOU HAVE  
7 UNPROTECTED SEX, YOU ARE RUNNING THE RISK OF BECOMING A  
8 FATHER WHETHER YOU WANT TO OR NOT. WE CAN SET UP A  
9 REGIME THAT SAYS IF YOU ARE A MAN AND YOU HAVE  
10 UNPROTECTED SEX, YOU ARE RUNNING THE RISK THERE MAY BE  
11 A PLACENTA OR CORD OR CORD BLOOD OR EVEN FETAL TISSUE  
12 CREATED WHICH WILL BE USED FOR RESEARCH. WE ARE  
13 SHAPING AND GUIDING PEOPLE'S EXPECTATIONS BY THE  
14 REGULATORY PROCESSES.

15 SO I DON'T THINK YOU NEED TO TRY AND GUESS  
16 WHAT PEOPLE'S EXPECTATIONS ARE AT THIS POINT AND HAVE  
17 THE REGULATORY PROCESS REFLECT THEM, BUT INSTEAD YOU  
18 CAN HAVE THE REGULATORY PROCESS REFLECT THE CURRENT  
19 STATE OF THE LAW AND SHAPE EXPECTATIONS ACCORDINGLY.  
20 SO WE URGE YOU NOT TO USE THE CONSENT REQUIREMENT FOR  
21 ANYONE OTHER THAN THE WOMAN. THANK YOU.

22 CO-CHAIR LO: CAN I ASK A QUESTION? I'M  
23 BEGINNING TO FEEL LIKE A STUDENT IN ALTA'S LAW SCHOOL  
24 CLASS. LET ME CHANGE THE HYPOTHETICAL A BIT. SO YOU  
25 HAVE A BIRTH MOTHER IN THE DELIVERY ROOM WHO WANTS TO

1 GIVE CORD BLOOD AND PLACENTA. SHE HAD AN OOCYTE DONOR  
2 AND THE OOCYTE DONOR, NOT THE WOMAN IN THE DELIVERY  
3 ROOM. WOULD YOU WANT CONSENT FROM THAT OOCYTE DONOR TO  
4 USE THE CORD BLOOD FOR RESEARCH? AGAIN, THE ANALOGY IS  
5 THE OOCYTE DONOR TO DONATE OOCYTES OR EMBRYOS, WE ARE  
6 REQUIRING THAT DONOR'S EXPLICIT CONSENT FOR STEM CELL  
7 RESEARCH.

8 SO THERE ARE LOTS OF ISSUES HERE. SOME OF IT  
9 STRIKES ME HAS TO DO WITH THERE BEING SOMETHING SPECIAL  
10 ABOUT REPRODUCTIVE MATERIALS, TRANSPLANTATION, AND STEM  
11 CELLS THAT GIVES IT A HEIGHTENED SORT OF SENSE OF WRONG  
12 IF THAT'S USED WITHOUT THE CONSENT FROM THE PERSON  
13 WHOSE DNA IT IS.

14 DR. KIESSLING: I'M ACTUALLY VERY PERSUADED  
15 BY THE ARGUMENT THAT WE JUST HEARD FROM THE PUBLIC. I  
16 THINK IT'S EXTREMELY IMPORTANT THAT WE NOT PUT IN PLACE  
17 ANY KINDS OF NEW CONSIDERATIONS OVER WHAT ARE WELL  
18 PRACTICED AND PRESUMABLY HAVEN'T HAD ANY PROBLEMS.

19 DR. PRIETO: I HAVE TO SAY THAT I FIND THAT  
20 ARGUMENT VERY PERSUASIVE TOO AND GO BACK TO SOMETHING  
21 EVERYONE WAS TRYING TO SAY EARLIER, THAT YOU CAN OFFER  
22 PEOPLE THE OPTION OF INVOLVEMENT. AND JUST AS A  
23 BIOLOGICAL FATHER HAS THE OPTION TO BE INVOLVED OR NOT  
24 INVOLVED; BUT IF THEY DO NOT EXERCISE THAT OPTION, WE  
25 DON'T GO LOOKING FOR THEM. THEY'VE GIVEN UP -- THEY

1 SURRENDERED IT. WE DON'T INCUR OTHER OBLIGATION  
2 BECAUSE OF THAT.

3 MR. SHESTACK: BUT THE PUBLIC, WE GOT A  
4 COMMENT FROM THE ACLU ATTORNEY THAT WAS SUGGESTING THAT  
5 CONSENT ONLY BE GRANTED TO THE MOTHER AND, FOR  
6 INSTANCE, JUST FOR CLARIFICATION -- IT WAS THE ACLU  
7 ATTORNEY'S SUGGESTION THAT ONLY THE MOTHER BE ALLOWED  
8 TO GIVE CONSENT. FOR INSTANCE, IF THERE WERE AN  
9 IDENTIFIED BIOLOGICAL FATHER, A MARRIED SPOUSE, THAT  
10 SPOUSE WOULD NOT BE ABLE TO DENY CONSENT OR AFFECT  
11 CONSENT IN ANY WAY.

12 MS. PASTORE: THE SAME AS IS TRUE FOR  
13 CONTINUATION -- YES, THAT IS OUR POSITION. AND IT'S  
14 THE SAME POSITION WITH REGARD TO THE CONTINUATION OR  
15 TERMINATION OF A PREGNANCY.

16 MR. SHESTACK: REALLY YOU'RE BASING THIS ON  
17 THE FACT THAT THE STEM CELL BLOOD AND THE PLACENTA IS  
18 THE PROPERTY OF THE WOMAN GIVING CONSENT IS WHAT IT  
19 SEEMS TO ME. IF THAT'S THE CASE, WELL, THEN ACTUALLY  
20 WE SHOULD PUT ALL CORD BLOOD IN THE BANK FOR 18 YEARS  
21 AND WAIT TILL THE AGE OF CONSENT OF THE ACTUAL NOW  
22 ADULT PERSON WHO IT IS AND ASK THEM IF THEY HAVE  
23 CONSENT BECAUSE GUARDIANSHIP IS OVER AND THEY'RE THE  
24 ACTUAL OWNERS.

25 MS. PASTORE: I ACTUALLY DON'T KNOW. I

1 UNDERSTAND YOU'RE OFFERING THAT AS A SORT OF OUT-THERE  
2 HYPOTHETICAL. I DON'T KNOW WHETHER WE HAVE A PROBLEM  
3 WITH THAT. BUT IT'S NOT A PROPERTY RIGHTS MODEL THAT  
4 GOVERNS REPRODUCTIVE RIGHTS. A WOMAN DOESN'T HAVE THE  
5 RIGHT TO CONTROL THE PREGNANCY BECAUSE THE BABY IS HER  
6 PROPERTY. IT'S BECAUSE HER BODY. IT'S NOT A PROPERTY  
7 RIGHTS MODEL. IT'S AN AUTONOMY MODEL, IT'S A LIBERTY  
8 MODEL, IT'S A PRIVACY MODEL, BUT IT'S NOT A PROPERTY  
9 MODEL.

10 DR. PRIETO: BUT THE CORD BLOOD, IF I COULD  
11 RESPOND TO THAT, THE CORD BLOOD IS NOT HER BODY, AND  
12 THE PLACENTA IS NO LONGER PART OF HER BODY. AND SO I  
13 THINK THAT THERE IS A DIFFERENT PRINCIPLE HERE INVOLVED  
14 IN THE USE OF YOUR GENETIC MATERIAL. AND IF THERE IS  
15 AN UNINVOLVED PROGENITOR WHO HAS FEELINGS AND OPINIONS  
16 ABOUT THE USE OF HIS OR HER GENETIC MATERIAL FOR  
17 RESEARCH, THEN WE SHOULD RESPECT THOSE RIGHTS. AND  
18 THAT'S DIFFERENT FROM CONTROL OF YOUR OWN BODY AND  
19 AUTONOMY.

20 MR. SHESTACK: I ACTUALLY WASN'T ASKING OUT  
21 OF AN ETHICAL ISSUE. I MEAN I THINK THAT ALL THESE  
22 THINGS ARE IN A CLOAKED WAY GUIDED BY PROPERTY LAWS AND  
23 THE GIANT FAILURE IN HOW WE DO BIOETHICS. BUT MY  
24 QUESTION WAS TO SAY, NOW, DO WE ACTUALLY OPEN OURSELVES  
25 UP POTENTIALLY TO MORE LITIGATION IF WE ACTUALLY HAVE A

1 COMMITTED SPOUSE LEGALLY RECOGNIZED IN EVERY WAY WHO  
2 DOES NOT WANT TO GRANT CONSENT? IS THERE CASE LAW THAT  
3 SOMEONE MOUNTED A CHALLENGE AND SUCCEEDED OR NOT  
4 SUCCEEDED, BUT IT HELD SOMETHING UP. AND FROM A PURELY  
5 PRACTICAL POINT OF VIEW, IS THIS MORE TROUBLE THAN IT'S  
6 WORTH OR LESS TROUBLE? I JUST CAN'T --

7 MS. PASTORE: I DON'T KNOW THE ANSWER AS TO  
8 WHETHER THERE'S A CASE ANYWHERE WHERE THIS HAS  
9 OCCURRED. I'M NOT AWARE OF ONE, BUT I WOULDN'T  
10 REPRESENT THAT THERE ISN'T ONE ANYWHERE BECAUSE THERE  
11 MAY BE ONE THAT I DON'T KNOW OF. BUT I THINK THAT THE  
12 COMMENT THAT WAS MADE OVER HERE BEFORE IS RIGHT, THAT  
13 WHEN YOU START TRYING TO SAY, WELL, LET'S GET  
14 EVERYBODY, THEN YOU START, WELL, WHAT ABOUT THAT OOCYTE  
15 DONOR? WHAT ABOUT THE LESBIAN COUPLE WHO INFORMALLY  
16 USED SPERM FROM SOMEBODY? YOU CAN START THINKING ABOUT  
17 A HUGE NUMBER. AND IF YOU LIMIT IT TO THE WOMAN, YOU  
18 ARE ACTUALLY DRASTICALLY REDUCING THE --

19 MR. SHESTACK: JUST ONE MORE QUESTION. DR.  
20 KIESSLING MAYBE COULD TELL US OR DR. TAYLOR. WHAT  
21 ACTUALLY IS THE AVAILABILITY OF BANKED CORD BLOOD NOW  
22 THAT HAS CONSENT OF BOTH PARENTS? MAYBE IT'S JUST NOT  
23 AN ISSUE. MAYBE AS OPPOSED TO SOMATIC CELL NUCLEAR  
24 TRANSFER, WHICH DOESN'T EXIST, OR FERTILIZED CELLS, BUT  
25 MAYBE THERE'S JUST AN ABUNDANCE OF THIS STUFF AND IT

1 DOESN'T MATTER. WE CAN JUST CREATE VERY STRICT RULES.  
2 PEOPLE BANK STEM CELLS IN EVERY HOSPITAL ACROSS THE  
3 COUNTRY AND BANK CORD BLOOD IN EVERY HOSPITAL ACROSS  
4 THE COUNTRY NOW, IT SEEMS.

5 DR. KIESSLING: NO. I THINK MOST CORD BLOOD  
6 IS BANKED WITH MATERNAL CONSENT, PERIOD.

7 MR. SHESTACK: AND IS THERE A LARGE SUPPLY OF  
8 IT?

9 DR. KIESSLING: THAT DEPENDS.

10 DR. OLDEN: A BANK FOR THERAPEUTIC PURPOSES,  
11 THOUGH.

12 CO-CHAIR LO: WE'VE GOT A LOT OF PEOPLE.  
13 ALTA AND SHERRY AND KEN, FRANCISCO, A LOT OF  
14 DISCUSSION.

15 MS. CHARO: FIRST, I'M VERY GRATEFUL FOR THE  
16 COMMENTS THAT WE HEARD, AND I DO THINK THAT THEY ARE  
17 VERY HELPFUL. I AGREE IN MANY RESPECTS WITH THE  
18 COMMENTS FROM THE ACLU, BUT NOT IN ALL. SPECIFICALLY  
19 THE DEGREE TO WHICH THIS HAS TO FOLLOW THE SAME MODEL  
20 AS THE RULES FOR COMMENCING OR TERMINATING A PREGNANCY,  
21 WHICH REALLY ARE DISTINCTLY ABOUT BODILY INTERESTS,  
22 AMONG OTHER THINGS, WHICH ARE NOT IMPLICATED HERE.

23 I FEEL LIKE THE BEST ANALOG, BECAUSE I'M  
24 CONSTANTLY SEARCHING FOR ANALOGS, IS IN THE PARENTAL  
25 DECISION TO ENROLL CHILDREN IN RESEARCH. AND WE DO

1 HAVE SOME PRECEDENTS THERE. I WAS JUST HUDDLING WITH  
2 BERNIE TO MAKE SURE THAT OUR MEMORIES MATCHED.

3 AND FOR RESEARCH THAT OFFERS NO -- OFFERS A  
4 PROSPECT OF MEDICAL BENEFIT FOR A CHILD, ONE PARENT'S  
5 CONSENT IS USUALLY ENOUGH, AND THAT'S COMPLETELY  
6 CONSISTENT WITH THE BANKING RULES THAT ALLOW MATERNAL  
7 CONSENT ONLY FOR THE BANKING OF CORD BLOOD, WHICH IS  
8 CURRENTLY BEING DONE FOR THE PURPOSES OF ADDRESSING A  
9 PROSPECT OF MEDICAL BENEFIT TO THE CHILD.

10 BUT WHEN YOU ARE DOING RESEARCH AND THERE'S  
11 NO PROSPECT OF DIRECT BENEFIT TO THE CHILD, WHERE IT'S  
12 BEING DONE FOR THE SAKE OF SCIENCE AND SOCIETY, WE  
13 TYPICALLY REQUIRE TWO PARENTS IF THE TWO PARENTS ARE  
14 AVAILABLE.

15 MR. SHESTACK: WHAT IF THAT'S COMPLETELY  
16 NONINVASIVE? FOR INSTANCE, THERE'S NO --

17 MS. CHARO: WHAT I'D LIKE TO DO WHILE WE'RE  
18 HAVING THIS DISCUSSION IS ACTUALLY GO AND CHECK THE  
19 CHILDREN'S RESEARCH REGS, IF WE CAN TAKE ENOUGH TIME TO  
20 DO THAT IN THE BACKGROUND. BERNIE HAS GOT THEM UP.  
21 AND TAKE A LOOK AND SEE WHETHER OR NOT THE WAY IT'S  
22 HANDLED THERE IS A GOOD BEGINNING START, BEGINNING  
23 POINT FOR THE DISCUSSION HERE ABOUT WHAT TO DO.

24 CO-CHAIR LO: SHERRY.

25 CO-CHAIR LANSING: AGAIN, I SO RESPECT ALL OF

1 THE COMMENTS THAT ARE COMING FROM THE PUBLIC AND FROM  
2 OUR GROUP HERE, BUT I HAVE TO SAY, AND NO ONE RESPECTS  
3 A WOMAN'S RIGHT TO CHOOSE ANY MORE THAN I DO, BUT I  
4 HAVE TO SAY WE ARE GOING INTO UNCHARTERED TERRITORIES.  
5 I AM REALLY TRYING VERY HARD TO DO WHAT'S BEST FOR THE  
6 SCIENCE AND TO AVOID ANY POTENTIAL LOOPHOLES THAT COULD  
7 REALLY HURT THE SCIENCE.

8 SO AT THIS POINT, AND, AGAIN, I SAY OVER AND  
9 OVER AND OVER AGAIN, WE CAN REEVALUATE THIS THREE  
10 MONTHS FROM NOW, SIX MONTHS FROM NOW, A YEAR FROM NOW,  
11 TWO YEARS FROM NOW AS THE SCIENCE PROGRESSES AND AS WE  
12 SEE.

13 BUT AT THIS POINT I THINK THAT, AS LONG AS  
14 THE MOTHER CAN USE IT FOR THERAPEUTIC USES FOR HER  
15 CHILD, WHICH WOULD BE THE IMMEDIATE CONCERN, I'M  
16 COMFORTABLE WITH LEAVING IT ALONE. WHEN YOU START TO  
17 GET INTO OTHER USES OF IT, THEN I SAY MAYBE IT'S GOING  
18 TO BE OKAY SIX MONTHS FROM NOW, BUT TODAY I JUST DON'T  
19 KNOW. AND I DON'T KNOW -- WHOEVER THOUGHT THAT WE'D BE  
20 SITTING HERE, YOU KNOW, WHEN I WAS GROWING UP, A CHILD  
21 WAS ADOPTED, WE WEREN'T SITTING HERE HAVING A PARENT  
22 CLAIM THE RIGHT OF THE CHILD 30 YEARS LATER. DO YOU  
23 KNOW? I'M GROWING UP THINKING YOU'RE ADOPTED, THAT'S  
24 IT, NEXT CASE.

25 WELL, I DON'T KNOW WHAT'S GOING TO HAPPEN



1 WHEN SOMEBODY IS GOING TO TRACK DOWN WHERE THEIR  
2 GENETIC MATERIAL WAS USED AND WHAT THEY'RE GOING TO  
3 FEEL ABOUT IT. JUST SO WE CAN PROTECT THE RIGHT OF  
4 THAT CHILD THAT COMES FROM THAT MOTHER, TODAY, THAT'S  
5 ALL I'M SAYING IS TODAY I FEEL COMFORTABLE WITH THIS.  
6 MAYBE NOT SIX MONTHS FROM NOW, MAYBE NOT SIX YEARS FROM  
7 NOW. I DON'T KNOW.

8 MR. SHEEHY: I HAVE TO APOLOGIZE FOR BEING A  
9 LITTLE BIT LATE. I DIDN'T REALLY HEAR THE SCIENCE  
10 PIECE OF THIS, BUT IN THE STRATEGIC PLANNING MEETING  
11 THAT WE HAD EARLIER THIS WEEK, WE WERE TALKING ABOUT  
12 ONE OF THE FIRST THINGS WE MAY DO IS SET UP A CORD  
13 BLOOD BANK. THAT ONE OF THE MOST PROMISING AVENUES FOR  
14 STEM CELL RESEARCH, A REAL MISSING LINK, IS THE USE OF  
15 CORD BLOOD, ESPECIALLY IN THE INSTANCE OF SICKLE CELL  
16 ANEMIA, THAT FOR SMALL CHILDREN, YOU MAY BE ABLE TO, IF  
17 YOU CAN TYPE AND CHARACTERIZE IT AND STORE IT, YOU MAY  
18 BE ABLE TO ACTUALLY ELIMINATE SICKLE CELL ANEMIA IN  
19 SMALL CHILDREN.

20 SO I THINK WE OUGHT TO TAKE, YOU KNOW, REALLY  
21 BRING IN PERHAPS BERT LUBIN AT CHILDREN'S HOSPITAL.  
22 MAYBE THIS IS SOMETHING THAT WE MIGHT WANT TO PUT OFF  
23 AND NOT NECESSARILY REIFY TODAY.

24 CO-CHAIR LANSING: COULD I JUST RESPOND. I'M  
25 SORRY. BUT WE STILL CAN DO THAT. IT'S JUST THAT WE'RE

1 SAYING THAT WE WOULD NEED THE CONSENT OF BOTH PARENTS.  
2 AM I CORRECT ABOUT THAT? THE GENETIC PARENTS, RIGHT,  
3 TO DO THAT, RIGHT?

4 CO-CHAIR LO: AGAIN, I THINK WE NEED TO --  
5 RIGHT NOW THERE ARE RULES IN PLACE WHERE DONATING CORD  
6 BLOOD FOR CURRENT BANKING EITHER FOR TREATMENT,  
7 AUTOLOGOUS TREATMENT, OR FOR DONATION TO OTHER CHILDREN  
8 WHO MAY NEED A TRANSPLANT. MY UNDERSTANDING IS YOU  
9 ONLY NEED THE CONSENT OF ONE PARENT.

10 MR. SHEEHY: SO THIS IS SIMPLY FOR RESEARCH  
11 PURPOSES. I APOLOGIZE.

12 CO-CHAIR LO: I GUESS WE'RE SAYING IT'S NOT  
13 JUST ANY RESEARCH. IT'S STEM CELL RESEARCH THAT MAY  
14 LEAD TO TRANSPLANTATION. I THINK IT'S -- THE STEM  
15 CELLS ARE DIFFERENT. TRANSPLANTATION IS DIFFERENT.  
16 AGAIN, I COME BACK TO THE ANALOGY THAT THERE'S A LOT OF  
17 MATERIAL THAT WOULD BE GREAT TO USE FOR  
18 TRANSPLANTATION; BUT IF WE CAN'T GET CONSENT FROM THE  
19 FAMILY, WE'RE NOT ALLOWED TO USE THAT KIDNEY. WE'RE  
20 NOT ALLOWED TO USE THAT LIVER.

21 DR. HALL: A LITTLE BIT LOUDER, PLEASE.

22 CO-CHAIR LO: I'M SORRY. I'M TRYING TO SAY  
23 THAT THERE'S SOMETHING SPECIAL ABOUT RESEARCH FOR THE  
24 DERIVATION OF STEM CELL LINES WHEN THEY'RE ULTIMATELY  
25 USED FOR TRANSPLANTATION THAT RAISES ISSUES THAT AREN'T

1 RAISED IN OTHER TYPES OF RESEARCH AND CERTAINLY AREN'T  
2 RAISED FOR AUTOLOGOUS USE OR OTHER USE OF STEM CELL  
3 TRANSPLANTATION. I WOULD JUST URGE US TO ERR ON THE  
4 SIDE OF BEING RESTRICTIVE NOW TO MAKE SURE THE ONLY USE  
5 WE'RE USING FOR STEM CELL DERIVATION ARE WHERE WE HAVE  
6 CONSENT FROM BOTH PARENTS. IF WE WANT TO READDRESS  
7 THIS LATER, BOTH DNA CONTRIBUTING PARENTS, IF WE WANT  
8 TO ADDRESS THIS LATER, AS SHERRY SAYS, WE CAN ALWAYS  
9 REDISCUSS THIS.

10 IN THE CONTEXT OF A BROADER DISCUSSION ABOUT  
11 CIRM INVOLVEMENT WITH STEM CELL BANKING AND  
12 TRANSPLANTATION, I THINK WE MAY WANT TO RELOOK AT THIS.  
13 BUT IT JUST STRIKES ME THAT WE OPEN OURSELVES UP TO A  
14 LOT OF CRITICISM IF WE SAY YOU CAN USE SOMETHING THAT  
15 HAS SPECIAL MEANING TO A PERSON IN RESEARCH THAT IS  
16 PARTICULARLY SENSITIVE WITHOUT HIS CONSENT. I JUST  
17 FIND THAT HARD.

18 DR. PRIETO: I THINK THAT THE ANALOGY TO  
19 TRANSPLANTATION IS PERHAPS THE BEST ONE. AND I DON'T  
20 WANT TO BE SO SWAYED BY PRACTICAL CONSIDERATIONS THAT  
21 WE FORGET THE ETHICAL PRINCIPLES HERE. IF WE'RE  
22 TALKING ABOUT RESEARCH INVOLVING THE USE OF YOUR  
23 GENETIC MATERIAL, THEN I THINK YOU SHOULD HAVE A RIGHT  
24 TO HAVE SOME SAY IN THAT. YOU MAY CHOOSE TO SURRENDER  
25 THAT RIGHT. I'M NOT SURE THAT OUR CURRENT LANGUAGE

1 ACCOMMODATES THAT. OR YOU MAY CHOOSE NOT TO EXERCISE  
2 THAT RIGHT. I THINK WE'RE OBLIGATED TO ASK FOR IT OR  
3 TO ATTEMPT TO OBTAIN IT.

4 DR. WAGNER: CAN I MAKE ANOTHER COMMENT?

5 CO-CHAIR LO: PLEASE. PLEASE, JOHN.

6 DR. WAGNER: JUST SO THAT THE PEOPLE ARE  
7 AWARE, THE MAJORITY OF CORD BLOOD UNITS THAT ARE  
8 AVAILABLE FOR RESEARCH HAVE BEEN EXCLUDED ACTUALLY IN  
9 TERMS OF THEIR BANKING POTENTIAL. THEY'RE INCLUDED  
10 ACTUALLY IN THE DELIVERY ROOM. SO THAT WHEN, FOR  
11 EXAMPLE, YOU COLLECT LESS THAN 50 MILLILITERS OF BLOOD,  
12 THEN THEY DO NOT MEET THE ELIGIBILITY FOR BANKING, AND  
13 THOSE SAMPLES ARE TYPICALLY THEN, IN SOME BANKS ANYWAY,  
14 THEN OBTAINED AND SENT TO DIFFERENT LABS THAT ARE  
15 INTERESTED IN USING THEM FOR RESEARCH PURPOSES.  
16 THERE'S NO GENETIC INFORMATION. THERE'S NO INFORMATION  
17 ON THE CORD BLOOD UNIT. THEY'RE COMPLETELY DELINKED.  
18 THEY DON'T HAVE ANY WAY OF GOING BACK AND ACTUALLY  
19 DOING ANYTHING IN TERMS OF GETTING ANY FURTHER CONSENT.  
20 IT DOESN'T EXIST BECAUSE THERE'S NOTHING LINKING THAT  
21 RIGHT NOW.

22 HOWEVER, THE ALTERNATIVE IS WHEN YOU THEN  
23 DECIDE THAT YOU WANTED A SPECIFIC CORD BLOOD UNIT,  
24 HOWEVER THAT IS DEFINED, AND IS ALREADY IN THE BANK,  
25 THERE IS A LINK BACK. BUT IT'S ONLY A MINOR UNITS

1 BECAUSE MOST OF THOSE WILL NOT BE USED FOR THE PURPOSE  
2 OF CREATING STEM CELLS, AT LEAST NOT TODAY. BUT BY FAR  
3 THE MAJORITY OF CORD BLOOD UNITS THAT ARE USED FOR  
4 RESEARCH HAVE NO IDENTIFIERS WHATSOEVER AT ANY TIME  
5 POINT.

6 CO-CHAIR LO: JOHN, COULD I ASK A TECHNICAL  
7 QUESTION? IN LIGHT OF THAT, IF YOU HAVE A COLLECTION  
8 OF CORD BLOOD THAT'S A FULL ENOUGH SAMPLE THAT IT COULD  
9 BE GIVEN TO A CORD BLOOD BANK TO BE USED FOR BONE  
10 MARROW TRANSPLANTATION, CORD BLOOD TRANSPLANTATION,  
11 WOULD IT BE HARMFUL TO TAKE OFF A TINY AMOUNT AND GIVE  
12 IT TO RESEARCHERS TO USE FOR DEVELOPMENT OF STEM CELLS?

13 DR. WAGNER: YES. RIGHT NOW THE MOST  
14 SIGNIFICANT PREDICTOR OF OUTCOME AFTER UMBILICAL CORD  
15 BLOOD TRANSPLANT IS CELL DOSE. RIGHT NOW YOU WOULDN'T  
16 TAKE ANYTHING OFF FOR ANY OTHER PURPOSE BECAUSE THAT'S  
17 SUCH A CRITICAL OUTCOME MEASURE.

18 CO-CHAIR LO: THANKS. WE HAVE ANOTHER PUBLIC  
19 COMMENT, AND THEN I'D LIKE TO TRY AND WRAP THIS UP.

20 MS. COEYTAUX: JUST A SHORT COMMENT.  
21 FRANCINE COEYTAUX AGAIN. IT FOLLOWS VERY NICELY ON  
22 WHAT WAS JUST SAID. AGAIN, LET'S REMEMBER THIS ISN'T  
23 SOMETHING THAT HAS TO HAPPEN IN AN EMERGENCY WHERE YOU  
24 HAVEN'T HAD A CHANCE TO TALK TO THE PEOPLE IN ADVANCE.  
25 THESE ARE PEOPLE WHO ARE DELIVERING. THEY'VE HAD TIME

1 TO THINK. YOU'VE BEEN MEETING WITH THEM. YOU CAN TALK  
2 TO THEM. IF YOU HAVE AN ISSUE ABOUT DEFINITION OF WHO  
3 THE OTHER PARENT IS, FOR NOW AT LEAST USE THE FACT THAT  
4 YOU HAVE TO FILL OUT A BIRTH CERTIFICATE. AND THERE'S  
5 EITHER ONE NAME THAT GOES DOWN OR TWO NAMES THAT GO  
6 DOWN. AND IF YOU WANT TO STICK WITH THAT, I'M NOT A  
7 LEGAL EXPERT, I DON'T KNOW WHAT THAT WILL DO, BUT AT  
8 LEAST IT'S A BIT BETTER THAN JUST SAYING IT'S JUST THE  
9 MOTHER.

10 AGAIN, I URGE YOU. LOOK AT THAT LANGUAGE.  
11 IT'S THERE FOR A REASON. IT WILL PROTECT YOU IN THE  
12 SENSE THAT YOU WILL HAVE LESS PEOPLE POTENTIALLY COMING  
13 AFTER YOU; I.E., THE FATHER OR THE PARTNER, WHOEVER THE  
14 OTHER PERSON IS. YOU WILL HAVE DONE YOUR BEST. AND IF  
15 THERE IS DISAGREEMENT, THEN THAT IS NOT A GIVER. I  
16 SUSPECT THAT YOU STILL WILL HAVE MOST OF THE PEOPLE WHO  
17 ARE POTENTIAL DONORS REALLY BE DONORS BECAUSE YOU HAVE  
18 TIME TO WORK WITH THEM IN ADVANCE.

19 CO-CHAIR LO: OKAY. WELL, THIS HAS BEEN --  
20 IT IS A COMPLICATED TOPIC. WE'VE HAD A LOT OF  
21 DIFFERENT VIEWS. I'M NOT SURE THAT WE HAVE AGREEMENT.  
22 ONE THING -- AND I'M ALSO MINDFUL THERE'S SOME OTHER  
23 ISSUES I WANTED TO GET TO BEFORE LUNCH WITH REGARDS TO  
24 THE ASSURANCES OF RECORDKEEPING, WHICH I THINK WILL  
25 ALSO ENGENDER A LIVELY DEBATE.

1                   SO MY SUGGESTION WOULD BE IF WE CAN WRAP THIS  
2 UP NOW, IT WILL BE GREAT. THIS MAY BE SOMETHING THAT  
3 WE MAY NOT WANT TO SPEND ALL THE TIME ON THIS JUST  
4 BECAUSE THERE ARE OTHER THINGS WE WANT TO DO.

5                   PROCEDURALLY, I'M NOT SURE WE HAVE AGREEMENT.  
6 I'M CERTAINLY WILLING TO ENTERTAIN A MOTION, A SECOND,  
7 AND AT LEAST A STRAW VOTE, NOT AN ACTUAL VOTE. I WOULD  
8 HOPE THAT WE CAN ACHIEVE NEAR UNANIMITY ON THIS RATHER  
9 THAN A SPLIT VOTE.

10                  DR. KIESSLING: WE HAVE A QUORUM NOW, DON'T  
11 WE?

12                  CO-CHAIR LO: WE HAVE A QUORUM. SO I'M GLAD  
13 TO ENTERTAIN A MOTION.

14                  MR. LANSING: SO --

15                  DR. KIESSLING: CAN I ASK A QUESTION? WHAT  
16 HAPPENED TO ALTA'S SUGGESTION ABOUT REARRANGING THE  
17 LANGUAGE? I THOUGHT THAT WAS A GOOD SUGGESTION.

18                  CO-CHAIR LO: WELL, WE HAVE A NUMBER OF  
19 THINGS WE CAN MOVE AND VOTE ON. I THINK THERE'S A LOT  
20 OF PEOPLE WHO ARE HEADING IN DIFFERENT DIRECTIONS.

21                  MS. CHARO: BERNIE, JUST A POINT OF ORDER,  
22 CONSIDERING THAT WE DON'T HAVE A CLEAR CONSENSUS ON THE  
23 DIRECTION WE WANT TO GO, AND WE ALSO HAVE LANGUAGE  
24 ISSUES, MIGHT IT MAKE SENSE TO TAKE SOME TIME DURING  
25 LUNCH TO TRY TO DRAFT TWO OR THREE ALTERNATIVE

1 PROVISIONS THAT TRY TO CAPTURE THE OPTIONS, AND THEN  
2 COME BACK TO IT AT THAT POINT WITH SOME ACTUAL  
3 LANGUAGE?

4 CO-CHAIR LO: I THINK THAT'S FINE, EXCEPT WE  
5 MAY LOSE THE QUORUM. WE CAN ALWAYS GO BACK TO ACTUALLY  
6 A SENSE OF THE COMMITTEE AND SAY THERE WERE X PEOPLE  
7 THERE AND A OVER X THOUGHT THIS AND B OVER X THOUGHT  
8 THAT.

9 CO-CHAIR LANSING: I GUESS MY QUESTION IS IF  
10 YOU START -- IF WE START WITH THE MOST CONSERVATIVE,  
11 WHICH THIS IS NOW, AND THEN SAY WE'RE GOING TO MEET  
12 AGAIN TO DISCUSS THIS AT A LATER TIME, WE CAN MEET  
13 AGAIN, I'D ALWAYS RATHER ERR ON THE SIDE OF BEING  
14 CONSERVATIVE AND THEN OPEN IT UP. SO MY QUESTION IS WE  
15 LEAVE THE LANGUAGE AS IT IS, WHICH IS WHAT WE WERE  
16 ORIGINALLY COMFORTABLE WITH, AND THEN KNOW THAT -- YOU  
17 KNOW, SET A TIME OR SUBCOMMITTEE TO DISCUSS IT SOME  
18 MORE AND COME BACK TO US AGAIN TO REOPEN IT. AS OF  
19 TODAY, THIS IS WHERE WE ARE.

20 DR. WAGNER: I COULDN'T HEAR THAT.

21 CO-CHAIR LANSING: I SAID THAT IF WE LEAVE  
22 THE LANGUAGE AS IT IS TODAY, IT IS, WE ALL AGREE, THE  
23 MOST CONSERVATIVE AND, THEREFORE, THE SAFEST AT THIS  
24 TIME, BUT THAT WE ARE GOING TO CONTINUE TO EXPLORE IT  
25 IN A SUBCOMMITTEE. ALTA, YOU KNOW, IS GOING TO



1 CONTINUE TO LOOK AT OTHER LANGUAGE, AND WE WILL REVISIT  
2 IT IN OUR NEXT MEETING, WHICH WILL BE -- I'M MAKING UP  
3 A TIME -- SIX MONTHS FROM NOW, FOUR MONTHS FROM NOW,  
4 WHATEVER.

5 DR. PETERS: SO THE APPROPRIATE MOTION, THEN,  
6 WOULD BE TO ACCEPT THE RECOMMENDATION TO KEEP THE  
7 ORIGINAL LANGUAGE. AND WE WOULD SIMPLY KNOW THAT THIS  
8 COULD BE CONTINUED AT THE NEXT OPPORTUNITY.

9 MS. CHARO: I WOULD NOTE, THOUGH, TED, THAT  
10 WE DID GET SOME GOOD COMMENTS ABOUT SOME LINGUISTIC  
11 ISSUES IN THE EXISTING RECOMMENDATION ASIDE FROM THE  
12 POLICY GOALS IN THAT RECOMMENDATION. SO RATHER THAN  
13 MAINTAIN THE LANGUAGE AS IT IS, WHICH I THINK WE  
14 RECOGNIZE AS BEING FLAWED, MAYBE COULD WE TABLE THE  
15 MOTION FOR THE MOMENT, AND THEN COME BACK WITH AT LEAST  
16 CORRECTED LANGUAGE AT SOME POINT THAT --

17 DR. PETERS: THAT IS A WISE SUGGESTION.

18 CO-CHAIR LANSING: THE REASON I'M CONCERNED,  
19 ALTA, AND I JUST -- WE HAVE TO HAVE THESE RULES IN  
20 PLACE. AND IF WE DON'T HAVE THESE RULES IN PLACE, WE  
21 CAN'T GIVE OUT MONEY. SO I'M AFRAID -- AGAIN, I DON'T  
22 KNOW THE ANSWER. I'M AFRAID THAT IF WE DON'T GET THESE  
23 IN PLACE, IF WE DON'T MAKE OUR RECOMMENDATIONS TO THE  
24 FULL ICOC BY OUR TIME, IT STARTS THE WHOLE PROCESS OVER  
25 AGAIN. WE CAN'T GIVE OUT THE MONEY. I JUST DON'T WANT

1 THIS PARTICULAR RULE TO IMPINGE THE SCIENCE GOING  
2 FORWARD.

3 CO-CHAIR LO: LET ME MAKE A SUGGESTION,  
4 DRAWING ON ALTA'S GOODWILL. IF ALTA CAN DRAFT SOME  
5 LANGUAGE THAT CARRIES OUT THE POLICY INTENT OF THE  
6 ORIGINAL LANGUAGE, BUT SHARPENS THE LANGUAGE TO ADDRESS  
7 SOME OF THE PROBLEMS WITH UNDEFINED TERMS, LET'S TRY  
8 AND CONSIDER THAT AS THE DIRECTION WE WANT TO GO BEFORE  
9 LUNCH. IF THAT DOESN'T CARRY, THEN I THINK WE HAVE A  
10 LOT MORE DISCUSSION TO TRY AND REACH AGREEMENT, FLESH  
11 OUT THE ISSUES MORE. LET'S GIVE ALTA A CHANCE TO  
12 DOUBLE-TASK, MULTITASK ON THIS.

13 I WOULD ACTUALLY LIKE TO MAYBE TAKE -- IF  
14 THAT'S OKAY WITH TED.

15 DR. PETERS: OH, YES.

16 CO-CHAIR LO: I WOULD LIKE TO TAKE A BRIEF  
17 BATHROOM BREAK, AND THEN COME BACK. THERE WERE SOME  
18 VERY INTERESTING AND IMPORTANT ISSUES HAVING TO DO WITH  
19 ASSURANCES AND RECORDKEEPING THAT I REALLY DO WANT TO  
20 GET TO BEFORE WE BREAK FOR LUNCH. IF WE TAKE A  
21 FIVE-MINUTE BREAK. THANK YOU VERY MUCH. IT'S BEEN A  
22 GOOD DISCUSSION.

23 (A RECESS WAS TAKEN.)

24 CHAIRMAN LO: WELL, WE CAN NEVER SAY THAT WE  
25 DON'T HAVE INTERESTING AND DIFFICULT ISSUES TO DISCUSS

1       HERE.  I NEVER NEED COFFEE TO STAY AWAKE BECAUSE THESE  
2       ARE SO INTELLECTUALLY CHALLENGING.

3                I WOULD LIKE TO KIND OF ADDRESS SOME OTHER  
4       ISSUES BECAUSE I THINK THERE'S LOTS OF PRESSING ISSUES  
5       THAT I DO WANT TO DEAL WITH, AND I WANT TO TRY AND --  
6       THERE ARE TWO ISSUES THAT I WANT TO MAKE SURE WE GET  
7       THE INPUT FROM PEOPLE ON THE PHONE BEFORE WE LOSE THEM.  
8       AND I'M TRYING TO -- IF SOMEONE COULD FLIP THOSE SLIDES  
9       BACK ON.  THANKS.  IT'S THE SLIDE 2.

10               GEOFF, CAN YOU HELP ME HERE?  HOPEFULLY THESE  
11       WILL BE RELATIVELY QUICK, BUT THEY'RE VERY IMPORTANT IN  
12       TERMS OF WHAT OUR REGULATIONS COVER AND HOW WE DEAL  
13       WITH COMPLICATIONS.

14               SO THE DEFINITION OF COVERED STEM CELL LINE,  
15       WHICH IS PAGE 2 IN YOUR HANDOUT, NO. 1 IN THE UPPER  
16       LEFT-HAND BOX.  AN ISSUE REALLY HAS TO DEAL WITH NOT  
17       WANTING TO HAVE ADULT STEM CELLS WHICH ARE NOT  
18       PLURIPOTENT SUBJECT TO THE SAME KIND OF DETAIL,  
19       OVERSIGHT, AND REGULATION AS PLURIPOTENT OR TOTIPOTENT  
20       STEM CELLS.

21               THERE WERE SOME CONCERNS RAISED BY SCIENTISTS  
22       AND RESEARCH INSTITUTIONS THAT WHAT WE PROPOSED IN  
23       FEBRUARY WAS NOT QUITE RIGHT.  AND THE PROBLEM CENTERS,  
24       IF YOU LOOK AT THE BOTTOM LEFT-HAND BOX,  
25       DIFFERENTIATION ALONG MULTIPLE CELL LINEAGES.  AND THE

1 PROBLEM IS WHAT'S A LINKAGE?

2 SO A HEMATOPOETIC STEM CELL THAT CAN PRODUCE  
3 PLATELETS, WHITE CELLS, AND RED CELLS, ARE THOSE THREE  
4 MULTIPLE LINEAGES? SO THE PROPOSED IS THAT WE REALLY  
5 ARE TALKING ABOUT PLURIPOTENT STEM CELLS. SO THE  
6 PROPOSED CHANGE IS THAT THE COVERED STEM CELL LINES  
7 MEANS A CULTURE-DERIVED HUMAN PLURIPOTENT STEM CELL  
8 POPULATION THAT IS CAPABLE OF SUSTAINED PROPAGATION AND  
9 SELF-RENEWAL TO DONOR CELLS OF EQUAL DEVELOPMENTAL  
10 POTENTIAL. THIS INCLUDES EMBRYONIC AND NON-EMBRYONIC  
11 STEM CELLS REGARDLESS OF TISSUE ORIGIN. AND WE ALSO  
12 SAY PLURIPOTENT MEANS CAPABLE OF DIFFERENTIATION INTO  
13 THE THREE LAYERS OF MESODERM, ECTODERM, AND ENDODERM.

14 AND I HOPE ZACH AND KEVIN, ZACH AND KEVIN,  
15 ARE YOU THERE?

16 DR. HALL: YES, WE ARE. WE'RE AGAIN TRYING  
17 TO PICK UP.

18 CHAIRMAN LO: WE'RE DEALING WITH PAGE 2 OF  
19 YOUR THICK SUMMARY, AND IT'S THE DEFINITION OF COVERED  
20 STEM CELLS. AND SUBSTITUTING PUTTING IN THE NOTION OF  
21 PLURIPOTENT TO REPLACE MULTIPLE CELL LINEAGES. DOES  
22 THAT GET THE RIGHT TARGET IN TERMS OF GETTING THE STEM  
23 CELL LINES WE WANT AND NOT DRAGGING IN ADULT STEM CELL  
24 LINES THAT DON'T RAISE THE SAME KINDS OF ETHICAL  
25 ISSUES?

1 DR. HALL: SO ONE QUESTION I WOULD HAVE,  
2 BERNIE, OUR DISCUSSION, MY SENSE, AS WE DISCUSSED,  
3 THERE IS MUCH WORK GOING ON, FOR EXAMPLE, WITH ADULT  
4 HEMATOPOETIC STEM CELLS, AND WE HAVE NO DESIRE TO SORT  
5 OF MARCH IN AND SAY HERE'S A NEW LEVEL OF REGULATIONS.  
6 HOWEVER, I THINK IF ONE LOOKS AT THE KIND OF  
7 EXPERIMENTS, FOR EXAMPLE, THAT IRV WEISSMAN IS DOING AT  
8 STANFORD, WHERE THEY PUT THEIR NOT PLURIPOTENT, BUT I  
9 THINK MULTIPOTENT CELLS INTO ANIMALS, AND THEY'RE --  
10 THEY DEEMED IT IMPORTANT TO MAKE A REVIEW OF THAT. SO  
11 THE QUESTION IS DO WE WANT TO WRITE IT IN SUCH A WAY TO  
12 COVER THOSE KINDS OF EXPERIMENTS OR NOT.

13 I MEAN IT IS A NARROW LINE ONE WALKS HERE.  
14 AND THE QUESTION IS HOW TO CRAFT IT SO THAT THE  
15 EXPERIMENTS WE CARE ABOUT BEING REVIEWED ARE REVIEWED,  
16 BUT THOSE THAT ARE ONGOING AND SORT OF HAVE BEEN GOING  
17 ON FOR YEARS ARE NOT ONES THAT WE INTRUDE OURSELVES  
18 INTO.

19 DR. EGGAN: I WOULD LIKE TO ECHO WHAT ZACH  
20 JUST SAID AND AGREE WITH IT. AND I THINK THE POINT  
21 THAT I WOULD LIKE TO RAISE, THE DIFFICULTY WITH THIS IS  
22 THAT, OF COURSE, THERE IS, I WOULD SAY, ONGOING DEBATE  
23 IN THE LITERATURE AS TO WHETHER OR NOT THERE ARE CELLS  
24 THAT EXIST NATURALLY IN THE BONE MARROW WHICH HAVE A  
25 MORE GENERALIZED DEVELOPMENTAL POTENTIAL. AND SO, IN

1 FACT, THERE ARE THOSE, I WOULD SAY, THAT FALL INTO TWO  
2 DIFFERENT CATEGORIES OF SCIENTISTS THAT ARE  
3 CARD-CARRYING MEMBERS OF A GROUP OF PEOPLE THAT BELIEVE  
4 THAT EACH OF THESE CELLS WOULD HAVE THESE  
5 CHARACTERISTICS, AND THEN THERE ARE OTHER SCIENTISTS  
6 WHICH DON'T BELIEVE THAT'S THE CASE.

7 AND SO I THINK THAT THIS SORT OF LEAVES YOU  
8 WITH AN OPERATIONAL DEFINITION WHICH IS GOING TO BE  
9 DIFFICULT FOR PEOPLE TO INTERPRET.

10 CHAIRMAN LO: SO LET ME -- IT STRIKES ME  
11 THERE'S THREE ISSUES HERE THAT YOU PHRASED, WHICH ARE  
12 ALL VERY IMPORTANT. ONE IS THAT WE DON'T WANT TO  
13 INCLUDE ADULT HEMATOPOIETIC STEM CELL LINES THAT ARE  
14 USED FOR ONLY HEMATOPOIETIC CELL RESEARCH AND EVENTUAL  
15 THERAPY BECAUSE THERE'S A READY AND EXISTING,  
16 WELL-DEVELOPED REGULATORY STRUCTURE AND A LOT OF  
17 EXPERIENCE.

18 SO THE CONCERN WAS THE ORIGINAL LANGUAGE WE  
19 HAD WAS SO BROAD THAT IT WOULD BRING IN THOSE ADULT  
20 STEM CELLS, AND I THINK THE NEW LANGUAGE EXCLUDES THEM.

21 NOW, ZACH -- LET ME COME TO ZACH'S POINT  
22 LATER. KEVIN RAISES THE QUESTION OF MAYBE IT'S  
23 PLURIPOTENT OR SOME PEOPLE THINK SO, BUT NOT EVERYBODY.  
24 I GUESS I WOULD HOPE THAT IT'S SORT OF THE SCIENTIFIC  
25 CONSENSUS THAT WHEN IT BECOMES SCIENTIFICALLY ACCEPTED

1 THAT A CERTAIN TYPE OF CELL IS PLURIPOTENT, THEN IT  
2 FALLS UNDER OUR LANGUAGE. BUT IF IT'S NOW SOME PEOPLE  
3 THINK SO, BUT A LOT OF OTHER PEOPLE DON'T, I'M NOT SURE  
4 THAT'S THE POINT AT WHICH YOU WANT TO DRAW THEM INTO  
5 OUR REGULATORY STRUCTURE.

6 ZACH RAISES ANOTHER POINT WHICH I THINK IS  
7 RIGHT. THERE MAY BE SOME TYPES OF RESEARCH WITH  
8 NONPLURIPOTENT STEM CELLS THAT RAISES ETHICAL CONCERNS  
9 THAT WE WOULD WANT TO REVIEW VERY CAREFULLY. AND THEY  
10 VOICED AN EXPERIMENT ABOUT REPLACING ALMOST AN ENTIRE  
11 MOUSE'S NEUROLOGICAL TISSUE WITH HUMAN NEURAL CELLS,  
12 AND IT RAISES THOSE KINDS OF CONCERNS EVEN THOUGH THE  
13 DERIVATION -- THE CELLS WE TRANSPLANTED ARE NOT FROM A  
14 PLURIPOTENT STEM CELL LINE. MAYBE WE NEED TO SAY WE  
15 WANT TO COVER ALL THESE STEM CELL LINES, BUT IN  
16 ADDITION, WE WANT TO COVER SOME OTHER RESEARCH THAT  
17 INVOLVES PARTICULARLY SENSITIVE TYPES OF  
18 TRANSPLANTATION INTO ANIMALS WITH NONCOVERED STEM CELL  
19 LINES. I DON'T KNOW. THAT'S SORT OF AN ADMINISTRATIVE  
20 REGULATORY NIGHTMARE, BUT I'M JUST THINKING THAT WHAT'S  
21 BOTHERSOME ABOUT THE WEISSMAN EXPERIMENTS IS NOT WHERE  
22 THEY GOT THE LINE, WHETHER IT'S A COVERED LINE OR NOT,  
23 BUT WHAT THEY INTENDED TO DO WITH IT.

24 ZACH, I THINK YOU'RE RIGHT. WE WANT TO COVER  
25 WEISSMAN'S PROPOSED EXPERIMENTS IN TERMS OF REGULATORY

1       OVERSIGHT, BUT I'M NOT SURE TINKERING WITH THE  
2       DEFINITION OF COVERED STEM CELL LINES IS GOING TO DO  
3       THAT.  AGAIN, I DEFER TO YOU SCIENTISTS WHO KNOW THIS  
4       MUCH BETTER THAN I DO.  ZACH, ANY THOUGHTS?

5                 DR. HALL:  WE WERE JUST HAVING AN OFF-LINE  
6       DISCUSSION HERE TRYING TO WORK IT OUT.  THE QUESTION IS  
7       WHETHER THE ISSUE OF CELL LINE GETS TO IT OR NOT.  AND  
8       KEVIN WAS JUST REMARKING, THAT, IN FACT, FOR EXAMPLE,  
9       IN THOSE CELLS, THE NEUROPROGENITORS ONE USES THAT DO  
10      MULTIPLY IN CULTURE BEFORE YOU ACTUALLY USE THEM.  AND  
11      THEREFORE, HOWEVER SORT OF ILL-DEFINED COULD BE  
12      CONSIDERED A CELL LINE.  IT'S NOT LIKE A PRIMARY  
13      ISOLETTE.  WHETHER THAT NOW WITH ADULT HEMATOPOIETIC  
14      STEM CELLS, I DON'T KNOW THE RANGE OF RESEARCH IN THAT  
15      FIELD, AND I DON'T KNOW TO WHAT EXTENT THAT WOULD  
16      REPRESENT SORT OF AN INCURSION ON THAT.  AND IF ANYBODY  
17      ELSE CAN OFFER EXPERT OPINION ON THAT, IT WOULD BE VERY  
18      USEFUL.

19                THE QUESTION IS I THINK WE HAVE SORT OF A  
20      GENERAL SENSE OF THE KIND OF THING WE WANT TO BE AWARE  
21      OF AND THE KIND OF THING WE WANT TO AVOID.  IT'S JUST,  
22      AS I SAID, THE QUESTION OF HOW TO CRAFT THE RIGHT WORDS  
23      TO HANDLE IT.  ONE POSSIBILITY WOULD BE TO CONTINUE TO  
24      WORK ON THAT.  IF WE CAN GET THE SENSE OF THE MEETING,  
25      WE CAN CONTINUE TO WORK ON THAT AND BE SURE OF ALL OUR



1       FACTS A LITTLE BIT FURTHER DOWN THE LINE. I WOULD  
2       WELCOME ANYBODY'S EXPERTISE ON THIS WHO CAN SPEAK WITH  
3       KNOWLEDGE AND AUTHORITY ABOUT IT.

4               DR. EGGAN: I'D JUST LIKE EXPAND ON THAT BY  
5       SAYING ONE THING. FOR INSTANCE, ONE CAN IMAGINE THAT  
6       ONE WOULD WANT TO IN THIS PARTICULAR ARENA CAPTURE  
7       THINGS LIKE THESE MASS T-CELLS WHICH ARE PRODUCED FROM  
8       HUMAN BONE MARROW, WHICH MAY HAVE A GENERALIZED  
9       POTENTIAL (UNINTELLIGIBLE PHONE TRANSMISSION) SAY, FOR  
10      INSTANCE, WHEN INJECTED INTO A BLASTOCYST MIGHT GIVE  
11      RISE TO A VARIETY OF DIFFERENT TISSUES. THEN, OF  
12      COURSE, THAT CULTURE WOULD BE A COVERED STEM CELL LINE.

13             BUT THEN, OF COURSE, SOMETHING LIKE BONE  
14      Marrow, SOME PEOPLE ALSO ARGUE HAS GENERALIZED  
15      POTENTIAL, BUT IS NOT COVERED. SO I THINK IT SATISFIES  
16      THE CONCERN, THE MORE I THINK ABOUT IT, WITH RESPECT TO  
17      BONE MARROW DERIVED CELLS, BUT I THINK THAT ZACH'S  
18      POINT IS RIGHT, THAT YOU NEED SOME SORT OF DEFINITION  
19      THAT HAS TO DO WITH THE OTHER CONCERN PARTICULARLY OF  
20      NEUROLOGICAL TISSUE. THAT IS REALLY WHAT PEOPLE ARE  
21      CONCERNED ABOUT HERE.

22             DR. HALL: THE QUESTION IS WHETHER AS  
23      WRITTEN, WHICH IS THE VERSION ON THE LEFT ON THAT PAGE,  
24      ISN'T THAT CORRECT, PAGE 2, THAT IS NOW, BERNIE AND  
25      GEOFF?

1                   CHAIRMAN LO: WELL, WE'RE PROPOSING THE  
2                   VERSION ON THE RIGHT WHICH TALKS --

3                   DR. HALL: I UNDERSTAND. BUT WHAT WE'RE  
4                   SAYING IS THAT THE PLURIPOTENT IS TOO -- DOESN'T  
5                   CAPTURE THE EXPERIMENTS WE WANT TO. IT COULD SAY  
6                   MULTIPOTENT. ANOTHER POSSIBILITY, HOWEVER, WOULD BE  
7                   JUST TO GO BACK TO THIS IDEA OF A STEM CELL LINE; THAT  
8                   IS, SOMETHING THAT HAS BEEN GROWN IN CULTURE BEFORE  
9                   IT'S BEING USED. ADULT HEMATOPOETIC CELLS GENERALLY  
10                  DON'T GROW IN CULTURE OR AREN'T GROWN IN CULTURE.

11                  WE WERE JUST HAVING AN OFF-LINE CONVERSATION  
12                  ABOUT WHETHER THE PRESENT VERSION IS ADEQUATE OR NOT.  
13                  THAT IS, IS IT BETTER TO STICK WITH THE CELL LINE IDEA,  
14                  THAT IT CAN PROPAGATE IN CULTURE. I THINK THAT WOULD  
15                  BE -- MAYBE YOU OUGHT TO SAY THAT SPECIFICALLY, THAT  
16                  FOR HUMAN EMBRYONIC STEM CELLS THAT HAVE BEEN  
17                  PROPAGATED IN CULTURE BEFORE USE, AND IT WOULD REQUIRE  
18                  REVIEW, OR HUMAN STEM CELLS, NOT EMBRYONIC, THAT HAVE  
19                  BEEN PROPAGATED IN CULTURE BEFORE USE EXPERIMENTALLY  
20                  WOULD REQUIRE REVIEW. MAYBE WE COULD GET SOME OPINIONS  
21                  ON THAT VERSION.

22                  DR. KIESSLING: I HAVE A MORE GENERIC  
23                  QUESTION. WHAT IS IT THAT WE'RE TRYING TO AVOID?

24                  CHAIRMAN LO: I THINK WE'RE TRYING TO AVOID  
25                  PUTTING ADULT STEM CELL RESEARCH THROUGH OVERSIGHT AND

1 REGULATIONS BEYOND WHAT IT NOW GOES THROUGH IN THE  
2 ABSENCE OF ANY REAL ETHICAL CONCERNS, THAT THE CURRENT  
3 OVERSIGHT SYSTEM FOR ADULT STEM CELL TRANSPLANTATION  
4 AND RESEARCH IS INADEQUATE.

5 DR. KIESSLING: THAT JUST MEANS AN ESCRO  
6 REVIEW, RIGHT? ALL ADULT STEM CELL RESEARCH NOW IS  
7 GOING TO GO THROUGH AT LEAST AN IRB AND ANIMAL CARE.  
8 SO YOU'RE TRYING TO AVOID PUTTING ADULT STEM CELL  
9 RESEARCH THROUGH AN ESCRO REVIEW.

10 CHAIRMAN LO: YEAH. THE ADULT --

11 DR. HALL: WE'RE LOSING YOU HERE. CAN WE GET  
12 A LITTLE BIT OF THE DISCUSSION?

13 CHAIRMAN LO: ANN KIESSLING IS ASKING WHAT  
14 THE GOAL, WHAT OUR CONCERN ABOUT ALL THE REGULATION IS.  
15 AND SHE RAISED THE POINT THAT ADULT -- THE ONLY  
16 DIFFERENCE FOR THE ADULT STEM CELL RESEARCHER WOULD BE  
17 SCRO REVIEW AND THAT THEY ALREADY NEED TO GO THROUGH  
18 IRB REVIEW TO GET THE DONATION. IF IT GOES IN ANIMALS,  
19 IT WOULD GO TO IACUC REVIEW.

20 I GUESS THE STEM CELL RESEARCHERS HAVE SAID  
21 THAT'S REALLY -- WE DON'T NEED THAT. IT'S A FAIR  
22 AMOUNT OF PAPERWORK FOR NO BENEFIT, AS WE CAN SEE. SO  
23 THEY SAY THAT'S OVERREGULATION.

24 DR. KIESSLING: BUT THERE'S AN ENORMOUS  
25 INTEREST IN THE PART OF ADULT STEM CELL RESEARCHERS TO

1 PROVE THAT THEY'RE PLURIPOTENT.

2 CHAIRMAN LO: ONCE THEY ARE PROVEN  
3 PLURIPOTENT, THEN THAT STEM CELL LINE FALLS UNDER ALL  
4 OUR REGULATIONS. OR WE COULD SAY THAT IF YOU DO THAT  
5 EXPERIMENT, THAT ALSO NEEDS TO COME BEFORE A SCRO. IN  
6 STAFF COMMENTS THAT WAS SORT OF OPTION 1.

7 DR. KIESSLING: THIS COMES DOWN ACTUALLY TO  
8 TRYING TO HAVE A CELL THAT DOES THIS TERM  
9 "TRANSDIFFERENTIATION." SO ADULT STEM CELL WORK THAT  
10 IS NOT GOING TO JUMP TISSUES --

11 DR. HALL: PLEASE REPEAT IT.

12 DR. KIESSLING: I'M SORRY, ZACH. SO WHAT I'M  
13 REALIZING IS IS THAT IT'S ADULT STEM CELL RESEARCH, THE  
14 POINT OF WHICH IS NOT TO JUMP TISSUE TYPE. THAT'S WHAT  
15 YOU'RE TRYING TO AVOID DRAGGING INTO THIS REVIEW.

16 CHAIRMAN LO: I THINK THAT'S RIGHT. AGAIN,  
17 I'M GOING TO DEFER TO JOHN WAGNER AND OTHERS WHO KNOW  
18 THIS RESEARCH BETTER.

19 DR. TAYLOR: I'M ACTUALLY JUST KIND OF  
20 CURIOUS ABOUT THE DEFINITION OF A LINE, A CELL LINE,  
21 AND WHETHER WE WANT TO BE AS RESTRICTIVE AS THAT WHEN,  
22 I GUESS, EXPLANTS OF INNER CELL MASSES COULD BE STUDIED  
23 UNDER PROTOCOLS, THEN THEY WOULD BE OUTSIDE OF THIS  
24 SORT OF JURISDICTION. IT SEEMS TO ME THAT WHAT WE'RE  
25 TRYING TO DO IS TO OVERSEE THE HUMAN EMBRYONIC CELL

1 EXPERIMENTATION. AND I DON'T KNOW THAT ESTABLISHING A  
2 STEM CELL LINE SHOULD NECESSARILY BE REQUISITE.

3 CHAIRMAN LO: SO THAT'S A POINT, AGAIN, I'M  
4 NOT SURE THAT'S COME UP BEFORE. THE REASON WE PUT STEM  
5 CELL LINE IS THAT, AGAIN, A LOT OF THE ADULT STEM CELL  
6 WORK IS AUTOLOGOUS DONATION WHERE A PERSON DONATES AND  
7 SOMETHING IS DONE OR NOT DONE IN THE LABORATORY TO  
8 MANIPULATE AND RETRANSFUSE. THAT'S NEVER CULTURED IN  
9 THE LAB. AGAIN, IT'S WAY OF TRYING TO SAY THAT'S  
10 WELL-REGULATED, SO WE DON'T HAVE TO DO IT.

11 ZACH VERY RIGHTLY POINTED OUT THAT WE WANT TO  
12 MAKE SURE WE INCLUDE EVERYTHING WE WANT TO INCLUDE, BUT  
13 WE DON'T WANT TO SWEEP IN UNDER OUR REGULATIONS THINGS  
14 THAT WE DIDN'T MEAN TO SWEEP IN. AND WE'RE HAVING A  
15 KIND OF SENSITIVITY, SPECIFICITY PROBLEM HERE.

16 DR. HALL: AN EXPLANT, IF YOU DO SAY THAT  
17 SOMETHING THAT'S PROPAGATED IN CULTURE, THAT IS, IT IS  
18 DERIVED IN CULTURE, THAT GENERALLY FOR PRIMARY  
19 EXPLANTS, THAT'S NOT THE CASE, ALTHOUGH I SUPPOSE IT  
20 COULD BE ARGUED THAT THEY DO UNDER CERTAIN CONDITIONS,  
21 AS KEVIN POINTS OUT, SKIN.

22 SO LET ME JUST SAY SO WHAT WE'RE INTERESTED  
23 IN, IT SEEMS TO ME, ARE EMBRYONIC CELLS. THAT'S CLEAR.  
24 AND PROBABLY FETAL CELLS THAT ARE MULTIPOTENT PERHAPS,  
25 AND THEN THE ISSUE OF ADULT STEM CELLS WHICH IF THEY

1 ARE ONLY SPECIFIC FOR WHO THEY ARE AND WHERE THEY ARE  
2 AND THE TISSUES THEY'RE IN, IT'S NOT A PROBLEM; BUT THE  
3 MINORITY VIEW IS THESE ACTUALLY HAVE -- TRY TO  
4 DIFFERENTIATE INTO STEM CELLS OF A BROADER SPECIFICITY  
5 OR DEDIFFERENTIATE INTO A BROADER SPECIFICITY, THEN IT  
6 BECOMES A PROBLEM. SO THAT, I THINK --

7 CHAIRMAN LO: MY SENSE --

8 DR. HALL: -- WOULD COVER THOSE. AND PART OF  
9 THE PROBLEM IS THAT THE LANGUAGE THAT'S USED IN GENERAL  
10 IN THE FIELD IS NOT ALWAYS PRECISE OR CONGRUENT AS USED  
11 BY DIFFERENT PEOPLE.

12 CHAIRMAN LO: MY RECOMMENDATION IS WE'RE NOT  
13 GOING TO RESOLVE THIS ONE TODAY BECAUSE WE'VE HAD A LOT  
14 OF INPUT FROM SCIENTISTS WHO DIDN'T LIKE OUR ORIGINAL.  
15 THEY PROPOSED SOMETHING SIMILAR TO WHAT IS NOW  
16 PROPOSED, BUT THAT'S NOT GOING TO WORK EITHER. MY  
17 SENSE IS WE NEED TO GO BACK AND THINK SOME MORE ABOUT  
18 THIS AND TRY TO GET A CONFERENCE CALL OR TAKE IT  
19 DIRECTLY TO THE ICOC. I JUST THINK THAT THE ISSUES  
20 HERE THAT WE'VE RAISED AREN'T GOING TO BE COVERED BY  
21 THE LANGUAGE THAT'S ON THE PAGE. I JUST DON'T THINK  
22 WE'RE GOING TO RESOLVE IT IN THE NEXT 15 MINUTES OR  
23 HOUR.

24 DR. KIESSLING: I DON'T SEE ANYTHING WRONG  
25 WITH THE ORIGINAL LANGUAGE.

1           CHAIRMAN LO: WELL, THE THOUGHT WAS THAT THAT  
2 BROUGHT IN ADULT STEM CELL RESEARCH WHERE IT WASN'T  
3 PLURIPOTENT. THAT IT ALL WAS GOING TO DIFFERENTIATE  
4 INTO DIFFERENT TYPES OF HEMATOPOIETIC CELLS.

5           DR. KIESSLING: DOESN'T PHRASE 2 COVER THAT?

6           CHAIRMAN LO: WELL, I'M NOT SURE WHAT  
7 MULTIPLE CELL LINEAGES WAS. SOME OF OUR COMMENTERS  
8 THOUGHT THAT THAT MEANT PLATELETS, WHITE CELLS, AND RED  
9 CELLS OF DIFFERENT LINEAGES.

10          DR. HALL: ...FOR CONSIDERATION AND IT MAY  
11 NOT WORK. THAT IS THE REAL -- PROBABLY THE MOST  
12 SENSITIVE ISSUE INVOLVES TRANSPLANTATION INTO THE  
13 BRAIN. AND MAYBE ONE SHOULD JUST ADD THAT SPECIFICALLY  
14 TO WHAT YOU HAVE ON THE VERSION ON THE RIGHT. THAT IS  
15 NEVER MIND GOING WITH FANCY DEFINITIONS. WHY DON'T WE  
16 SAY WHAT IT IS WE'RE I WORRIED ABOUT? I THINK IF  
17 YOU'RE PUTTING HUMAN SKIN CELLS INTO MOUSE SKIN, I  
18 DON'T THINK ANYBODY IS GOING TO WORRY ABOUT THAT. I  
19 THINK IF YOU ARE PUTTING BLOOD-FORMING CELLS, SAY, INTO  
20 MICE, I DON'T THINK WE'RE WORRIED ABOUT THAT OR LIVER  
21 CELLS OR PANCREAS CELLS.

22          IT IS VERY SPECIFICALLY, I THINK, THE BRAIN  
23 THAT PEOPLE WORRY ABOUT. AND I THINK THE ISSUES THERE  
24 AS MUCH REVOLVE AROUND THE PUBLIC UNEASINESS ABOUT  
25 THESE KINDS OF EXPERIMENTS AS AROUND ANY KIND OF REAL

1 DANGER. I THINK MOST OF US IN THE FIELD BELIEVE YOU  
2 HAVE -- IT WOULD BE HARD TO IMAGINE BEING ABLE TO  
3 CREATE AN ANIMAL BRAIN THAT WOULD HAVE ANY HUMAN  
4 CHARACTERISTIC THAT ONE COULD RECOGNIZE OR ONE WOULD BE  
5 DISTURBED BY IT, YET IT IS A VERY DISTURBING KIND OF  
6 EXPERIMENT FOR MEMBERS OF THE PUBLIC. I THINK FOR THAT  
7 REASON WE NEED TO PAY CAREFUL ATTENTION TO IT AND GIVE  
8 THOUGHTFUL AND CAREFUL CONSIDERATION, AS STANFORD DID,  
9 FOR THOSE KINDS OF EXPERIMENTS. THAT IS A PROPOSAL  
10 THAT MAYBE PEOPLE COULD DISCUSS.

11 CHAIRMAN LO: WELL, I GUESS MY -- AS THE  
12 MODERATOR, SORT OF WATCHING THE CLOCK TICK IN MY HEAD,  
13 I THINK I HAVE A SENSE OF WHERE WE'RE GOING TO GO WITH  
14 THIS, BUT I THINK IT IS GOING TO BE HARD TO CRAFT THE  
15 EXACT LANGUAGE. AGAIN, I DON'T THINK OUR TIME NOW WITH  
16 THE NUMBER OF PEOPLE WE HAVE IS WORTH PURSUING THIS ONE  
17 FURTHER EXCEPT TO SAY THAT WHAT WAS PROPOSED IN YOUR  
18 HANDOUT DOESN'T QUITE DO THE TRICK YET. I THINK WE'RE  
19 GOING TO TRY AND FIX THAT. I KNOW ZACH HAS THOUGHT  
20 ABOUT HAVING IT SEPARATE. WE ALSO WANT TO COVER ADULT  
21 STEM CELLS TRANSPLANTED INTO THE BRAIN. WE HAVE TO  
22 CRAFT THAT LANGUAGE. I THINK WE'RE TALKING ABOUT  
23 ANOTHER CONFERENCE CALL.

24 MR. LOMAX: BERNIE, IF I MAY, I THINK THE  
25 OTHER THING TO REALLY BE AWARE OF, AS SOMEONE WHO'S



1 QUITE INTIMATE WITH THIS REGULATION, I JUST WANT TO  
2 POINT OUT THE CRITICAL FACTOR IN TERMS OF ACHIEVING THE  
3 INTENT, WHICH ZACH BEGAN TO DESCRIBE, IS NOT SIMPLY THE  
4 DEFINITION, BUT THE INTERACTION BETWEEN THE DEFINITION  
5 AND SECTION 100070, WHICH OUTLINES UNDER WHAT  
6 CONDITIONS WHAT TYPE OF REVIEW IS REQUIRED BY THE SCRO.  
7 SO IT'S NOT SIMPLY A CASE OF FIXING IT WITH THAT, BUT  
8 IT'S ENSURING THAT THE INTERACTIVE QUALITY OF THE  
9 DEFINITION AND THE SPECIFIC REQUIREMENTS IS EXACT.

10 AND I WOULD AGREE WITH YOU, THAT THAT IS  
11 SOMETHING I THINK WE NEED TO JUST SORT OF WORK THROUGH  
12 VERY CAREFULLY.

13 CHAIRMAN LO: OKAY. SO WITH THE CONCURRENCE  
14 OF THE GROUP, WHAT I'D LIKE TO SUGGEST IS THAT WE SEND  
15 THIS ONE BACK TO THE DRAWING BOARD WITH THE COMMENTS  
16 TODAY TO GUIDE US, AND WE'RE GOING TO HAVE TO COME BACK  
17 WITH ACTUAL LANGUAGE WE CAN APPROVE.

18 I WOULD NOW LIKE TO SORT OF MOVE ON TO THE  
19 ISSUE OF THE CARE OF COMPLICATIONS OF OOCYTE DONATION.  
20 IF SOMEONE CAN JUST SWITCH TO THE VERY LAST SLIDE.

21 WE WERE WIDELY PRAISED FOR REQUIRING THAT AN  
22 OOCYTE DONOR WHO SUFFERS IMMEDIATE DIRECT AND PROXIMATE  
23 COMPLICATIONS HAVE MEDICAL CARE THAT'S FREE TO HER.  
24 AND, AGAIN, AS A MATTER OF PHRASING IT RIGHT -- IT'S  
25 THAT VERY LAST SLIDE. THANK YOU, SCOTT. A NUMBER OF

1 CONCERNS ABOUT THE WAY IT WAS PHRASED DIDN'T  
2 NECESSARILY LEAVE IT OPEN FOR THE COMMERCIAL SPONSOR OF  
3 RESEARCH ASSUMING THE COST. AND THEY THOUGHT THAT WE  
4 WERE TOO PRESCRIPTIVE.

5 AND THE LANGUAGE THAT WE'RE NOW SUGGESTING, I  
6 THINK, GIVES THE INSTITUTION OPTIONS FOR ACHIEVING THE  
7 GOAL. AND PROPOSED LANGUAGE IS THE CIRM-FUNDED  
8 RESEARCH INSTITUTION SHOULD ASSURE THAT PAYMENT FOR ANY  
9 MEDICAL CARE REQUIRED AS A DIRECT AND PROXIMATE RESULT  
10 OF OOCYTE DONATION -- I THINK WE HAVE TO PUT IN  
11 SOMETHING CIRM-FUNDED RESEARCH -- IS AVAILABLE FROM A  
12 SOURCE OTHER THAN THE DONOR OR HER HEALTH INSURER.

13 ACTUALLY I THINK ELLEN AURITI HAD DIFFERENT  
14 LANGUAGE. I'M READING THIS. I'M SORRY. I'M READING  
15 THE WRONG THING. ERASE WHAT I JUST SAID. WHAT IS ON  
16 YOUR BOARD AS A SLIDE, IF SOMEONE CAN TRY AND E-MAIL  
17 THIS LANGUAGE TO JOHN WAGNER, ZACH HALL, AND KEVIN  
18 EGGAN SO THEY CAN SEE IT. I'M SORRY, GUYS. LET ME  
19 START THE CLOCK.

20 THE PROPOSED LANGUAGE IS THE CIRM-FUNDED  
21 INSTITUTION SHALL DEVELOP PROCEDURES TO ENSURE THAT AN  
22 INDIVIDUAL WHO DONATES OOCYTES FOR CIRM-FUNDED RESEARCH  
23 HAS ACCESS TO MEDICAL CARE THAT IS REQUIRED AS A DIRECT  
24 AND PROXIMATE RESULT OF THAT DONATION AT NO COST TO THE  
25 DONOR SO THAT THEY CAN BUY INSURANCE, THEY CAN PAY FOR

1 IT OUT OF POCKET, THEY CAN ASK THE COMMERCIAL SPONSOR  
2 OF THE RESEARCH TO DO IT AS LONG AS IT'S NO COST TO THE  
3 WOMAN DONATING WHO SUFFERS THE ADVERSE CONSEQUENCE.

4 THIS IS JUST A WAY TO GIVE MORE OPTIONS TO  
5 THE INSTITUTION AS TO HOW TO FUND THIS KIND OF CARE.  
6 ANY CONCERNS ABOUT THE PROPOSED LANGUAGE?

7 DR. EGGAN: I HAVE A CONCERN, AND THAT IS  
8 THAT MOST -- AND ANN CAN CHIME IN TO SUPPORT OR REFUTE  
9 THIS, BUT MY IMPRESSION IS THAT MOST WIDELY AVAILABLE  
10 HEALTH INSURANCE OPTIONS WHICH EXIST FOR OOCYTE DONORS  
11 BASICALLY SORT OF RELY ON THAT PERSON'S OWN HEALTH  
12 INSURANCE TO COVER SOME OF THE COST. AND AS I SAID,  
13 ANN MAY KNOW MORE ABOUT THIS THAN I DO, BUT I'M WORRIED  
14 ABOUT, YOU KNOW, THIS SPECIFIC LANGUAGE THAT SAYS FROM  
15 A SOURCE OTHER THAN THE DONOR OR HER HEALTH INSURER.  
16 BECAUSE I JUST DON'T KNOW THE CURRENT STRUCTURE OF THE  
17 INSURANCE SITUATION IN THE UNITED STATES IS GOING TO  
18 STICK WITH THIS. ANN, DO YOU SOMETHING TO SAY ABOUT  
19 THAT?

20 DR. KIESSLING: WELL, YOU'RE RIGHT. I MEAN  
21 SOME OF THE RIDER POLICIES THAT YOU CAN GET DONORS --  
22 BOB IS GOING TO KNOW MORE ABOUT THIS THAN I DO -- IT  
23 RELIES ON THE FACT THAT THAT INDIVIDUAL HAS HER OWN  
24 HEALTH INSURANCE. BUT YOU CAN GET THE INSURANCE  
25 COMPANY TO WRITE A DIFFERENT KIND OF POLICY FOR

1 SOMEBODY DONATING FOR RESEARCH. YOU CAN ACTUALLY --  
2 THERE'S TWO OR THREE COMPANIES, AND THEY WILL WRITE A  
3 POLICY THAT COVERS THAT WOMAN INDEPENDENT OF HER OWN  
4 INSURANCE COVERAGE. IT'S JUST MORE EXPENSIVE.

5 DR. TAYLOR: JUST TO COMMENT, THE NEW  
6 LANGUAGE, WHICH I BELIEVE IS BEING E-MAILED TO YOU AS  
7 WE SPEAK, HAS TAKEN OUT THE CLAUSE ABOUT HER OWN HEALTH  
8 INSURER. SO IT'S A LITTLE BIT MORE GENERIC AND I THINK  
9 MORE PALATABLE AS A RESULT.

10 CHAIRMAN LO: DONATION AT NO COST TO THE  
11 DONOR. I THINK WE MEANT, BASED ON OUR DISCUSSION LAST  
12 TIME, TO SAY NO DEDUCTIBLES, NO COPAYMENTS. IT'S  
13 REALLY FREE TO HER.

14 AND I GUESS THE OTHER THING IS MY HOPE WOULD  
15 BE CIRM WOULD BE WILLING TO FUND THE COST OF SUCH  
16 INSURANCE AS A LINE ITEM IN THE BUDGET SO THAT, AGAIN,  
17 WE'RE NOT ASKING THE RESEARCHER TO TAKE ON OR THE  
18 INSTITUTION TO TAKE ON COSTS THAT ARE HIDDEN COSTS. IS  
19 THIS SOMETHING WE CAN AGREE ON, THIS NEW LANGUAGE? IT  
20 WAS ACTUALLY SUGGESTED BY ACTUALLY UCOP, ELLEN AURITI,  
21 BASED ON SOME OTHER DISCUSSIONS.

22 DR. OLDEN: I LIKE THE NEW LANGUAGE.

23 CHAIRMAN LO: YOU WANT TO MAKE A FORMAL  
24 MOTION?

25 DR. OLDEN: I SO MOVE THAT WE ACCEPT IT.

1                   CHAIRMAN LO: LET'S GET THE MOTION ON THE  
2 FLOOR, AND THEN -- THANK YOU FOR REMINDING ME ABOUT  
3 PUBLIC DISCUSSION. LET ME JUST FORMALLY GET THE  
4 MOTION.

5                   DR. TAYLOR: SECOND.

6                   CHAIRMAN LO: NOW PUBLIC COMMENT, PLEASE.

7                   MR. SIMPSON: VERY QUICKLY. JOHN SIMPSON  
8 FROM FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I  
9 THINK THE LANGUAGE IS VERY GOOD EXCEPT FOR ONE THING.  
10 I THINK IT'S REDUNDANT WHEN YOU SAY DIRECT AND  
11 PROXIMATE. I THINK ALL YOU NEED TO SAY IS AS A DIRECT  
12 RESULT OF THAT DONATION.

13                   MS. CHARO: WE HAD THAT COMMENT IN THE  
14 WRITTEN SUBMISSIONS, AND THE CONVERSATIONS THAT  
15 RESULTED CONCLUDED THAT ACTUALLY THE WORDS DO HAVE  
16 SEPARATE MEANINGS. ANYBODY WHO'S TAKEN TORT LAW KNOWS  
17 THAT. THEY SPEND WEEKS DISCUSSING THE FACT THAT THE  
18 TWO REALLY DO HAVE SEPARATE MEANINGS, AND THERE IS  
19 SIGNIFICANT REASONS TO ADD PROXIMATE, AND THAT'S TO  
20 CLARIFY WHAT HAPPENS WHEN THERE ARE SIGNIFICANT  
21 INTERVENING AND SUPERSEDING CAUSES FOR PROBLEMS THAT  
22 TAKE PLACE AFTER THE INITIAL EVENT. SO THIS ACTUALLY  
23 TRACKS THE KIND OF LANGUAGE YOU WOULD SEE FROM ORDINARY  
24 TORT LAW PROVISIONS.

25                   CHAIRMAN LO: SO THIS IS MEANT REALLY TO

1 APPLY TO HYPERSTIMULATION -- OVARIAN HYPERSTIMULATION  
2 SYNDROME AND NOT TO SOMETHING ALLEGEDLY HAPPENING 20,  
3 30 YEARS DOWN THE ROAD.

4 MS. CHARO: EXACTLY. THE NOTION OF DIRECT  
5 CAUSATION CAN ALLOW FOR A RIPPLE EFFECT THAT GOES OUT  
6 FOR AN INDEFINITE PERIOD OF TIME AND IS STILL  
7 CONSIDERED DIRECT REGARDLESS OF HOW MANY CONTRIBUTING  
8 CAUSES NOW ARE REALLY THE SUBSTANTIAL FACTOR FOR THE  
9 ULTIMATE OUTCOME OF INTEREST.

10 CHAIRMAN LO: SO ANY OTHER DISCUSSION? WE  
11 ACTUALLY DON'T HAVE A QUORUM ANYMORE, BUT WE CAN TAKE A  
12 SENSE OF THE MEETING. AND SO LET'S TRY AND DO THAT.  
13 HOW MANY APPROVE OF THE MOTION AS GIVEN? ANY  
14 OBJECTIONS? OKAY. SO WE HAVE --

15 MR. TOCHER: IF I CAN JUST MAKE A  
16 CLARIFICATION FOR THE RECORD. HOW MANY PEOPLE DO WE  
17 HAVE ON THE PHONE? HOW MANY VOTING MEMBERS ON THE  
18 PHONE?

19 CHAIRMAN LO: ZACH AND KEVIN, YOU'RE STILL ON  
20 THE PHONE?

21 DR. EGGAN: I'M HERE. ZACH HAD TO STEP OUT  
22 OF THE ROOM FOR A MOMENT, SO HE WASN'T PART OF THAT  
23 LAST VOTE.

24 CHAIRMAN LO: JOHN WAGNER, ARE YOU STILL ON  
25 THE PHONE? SO IT'S ONE ON THE PHONE PLUS -- JENN, CAN

1 YOU COUNT THE PEOPLE IN THE ROOM THAT ARE VOTERS? A  
2 NUMBER OF PEOPLE HAVE LEFT, SO WE DON'T HAVE A QUORUM,  
3 BUT WE HAVE A UNANIMOUS SENSE OF THE COMMITTEE.

4 MS. GREENFIELD: I WAS WONDERING WHY THE  
5 "ANY" HAS BEEN DELETED IN THIS VERSION.

6 CHAIRMAN LO: I'M SORRY. HELP US.

7 MS. GREENFIELD: ACCESS TO MEDICAL CARE. IN  
8 THE ORIGINAL LANGUAGE, YOU HAVE ANY MEDICAL CARE.

9 MS. CHARO: AND WHAT WOULD BE THE DIFFERENCE  
10 IN THE MEANINGS BETWEEN THE TWO PHRASES?

11 MS. GREENFIELD: WELL, I THINK IT'S JUST A  
12 BROADER DEFINITION OF WHAT MEDICAL CARE MIGHT BE  
13 SINCE --

14 CHAIRMAN LO: I MEAN I DON'T --

15 MS. GREENFIELD: I JUST WONDERED WHY THE WORD  
16 WAS DELETED.

17 MS. CHARO: PROBABLY JUST BECAUSE WHEN YOU  
18 REWRITE THINGS, YOU'RE ALWAYS TRYING TO JUST MAKE THEM  
19 AS CRISP AS YOU CAN GIVEN HOW CONVOLUTED THEY ALREADY  
20 ARE.

21 MS. GREENFIELD: OKAY. THINGS LIKE EMERGENCY  
22 CARE, FOR INSTANCE.

23 MS. CHARO: WOULD BE MEDICAL CARE.

24 CHAIRMAN LO: WE'RE NOT MEANING TO RESTRICT  
25 IT IN ANY WAY. WE'RE JUST TRYING TO SIMPLIFY THE

1 LANGUAGE. THANKS FOR THAT.

2 DID WE GET A TALLY ON THAT LAST VOTE?

3 DR. PETERS: IT'S THIS WORDING --

4 MS. ROSAIA: YOU DIDN'T GET DR. PRIETO ON THE

5 LAST VOTE.

6 DR. PRIETO: ON THIS LANGUAGE THAT WAS UP

7 WHEN I LEFT, VOTE TO ACCEPT IT.

8 CHAIRMAN LO: THAT'S THE MOTION, TO ACCEPT

9 IT.

10 DR. PRIETO: YES.

11 CHAIRMAN LO: SO WE'VE GOT A UNANIMOUS SENSE

12 OF A LARGER COMMITTEE. OKAY. GOOD. THANK YOU VERY

13 MUCH.

14 NOW I DO WANT TO GET TO WHAT I THINK ARE VERY

15 IMPORTANT AND QUITE NOVEL QUESTIONS HAVING TO DO WITH

16 RECORDKEEPING AND COMPLIANCE. AGAIN, SCOTT, IF I MAY

17 IMPOSE ON YOU. WE HAD A NUMBER OF COMMENTS FROM

18 MULTIPLE SOURCES REALLY ASKING US TO DO MORE WITH

19 REGARD TO RECORDKEEPING AND ASSURANCES OF FUNDS. AND I

20 FOUND IT HELPFUL CONCEPTUALLY, AT LEAST FOR ME, TO

21 THINK OF THESE AS QUESTIONS, ISSUES THAT WERE RAISED

22 THAT WE REALLY DIDN'T HAVE A CHANCE TO FULLY DISCUSS

23 BEFORE OUR FEBRUARY SUBMISSION AND I THINK ARE

24 IMPORTANT AND NEED TO BE ADDRESSED BY CIRM.

25 FIRST QUESTION IS WHAT INFORMATION SHOULD BE



1 COLLECTED, AND THERE ARE A NUMBER OF ADDITIONAL TYPES  
2 OF INFORMATION IN ADDITION TO WHAT WE HAD PROPOSED THAT  
3 WERE RECOMMENDED. THERE'S A SUBQUESTION TO THAT IN  
4 THAT SOME OF THAT INFORMATION REALLY DID HAVE TO DO  
5 WITH CIRM-FUNDED RESEARCH, BUT HAD TO DO WITH OTHER  
6 THINGS GOING ON AT THAT RESEARCH INSTITUTION THAT HAD  
7 CIRM FUNDING. AND SHOULD WE TRY AND DRAW IN THE -- WE  
8 WERE REQUESTED TO SORT OF USE THE CIRM FUNDING AS A  
9 LEVER TO GET OTHER DISCLOSURE, OTHER RECORDKEEPING.

10 SECOND QUESTION IS WHO IS RESPONSIBLE FOR  
11 COLLECTING THE INFORMATION, BASICALLY STANDING BEHIND  
12 IT. AND ONE SUGGESTION THAT WAS MADE IS THAT THE HEAD  
13 OF THE ORGANIZATION GETTING CIRM FUNDING, THE  
14 PRESIDENT, CHANCELLOR, CHIEF EXECUTIVE, WHATEVER, SIGN  
15 OFF ON THE ASSURANCE TO CIRM THAT ALL THE REGULATIONS  
16 WERE FOLLOWED. THIS GOES BEYOND WHAT CURRENTLY IS THE  
17 CASE.

18 WHEN I ASKED AROUND, THAT'S USUALLY  
19 DELEGATED. FOR EXAMPLE, IN OUR PLACE IT'S THE VICE  
20 CHANCELLOR FOR RESEARCH WHO TAKES THE REPORTS FROM THE  
21 IACUC AND IRB AND SCRO AND SIGNS A STATEMENT SAYING  
22 THAT WE COMPLY.

23 THIS IS ASKING TO BE KICKED UP TO THE HEAD  
24 HONCHO SO THAT PERSON IS RESPONSIBLE. THERE'S ALSO A  
25 SUGGESTION THAT AN OUTSIDE AUDITOR COME IN TO EVERY

1 CIRM-FUNDED INSTITUTION TO AUDIT THEM TO ASSURE  
2 COMPLIANCE. SO THE QUESTION IS DO WE PUT  
3 RESPONSIBILITY PRIMARILY ON THE INSTITUTION ITSELF? DO  
4 WE CALL FOR AN OUTSIDE AUDIT? AND THESE ARE IMPORTANT  
5 QUESTIONS TO ADDRESS.

6 THEN THE THIRD ISSUE WITH REGARD TO  
7 RECORDKEEPING IS WHO RECEIVES WHAT INFORMATION OR WHICH  
8 INFORMATION. AND CERTAINLY AT THE BASIC LEVEL, THE  
9 INSTITUTION IS GOING TO COLLECT IT, AND SOMEONE AT THE  
10 INSTITUTION, WHETHER IT'S THE VICE CHANCELLOR OR THE  
11 CHANCELLOR, NEEDS TO LOOK AT THAT INFORMATION,  
12 SYNTHESIZE THE REPORT, AND SIGN IT. WHO ELSE GETS THE  
13 INFORMATION, AND YOU CAN DISTINGUISH, I THINK, BETWEEN  
14 ALL THE INFORMATION THAT GOES INTO THE REPORT OR SORT  
15 OF THE SUMMARY OF THE REPORT OR THAT ATTESTATION OR  
16 AFFIRMATION. SO IT COULD AUTOMATICALLY GO TO CIRM. IT  
17 COULD AUTOMATICALLY GO TO THE LEGISLATURE. AND IT  
18 COULD AUTOMATICALLY BE MADE AVAILABLE TO THE PUBLIC.

19 BY IT, I'M USING THAT AMBIGUOUSLY BECAUSE IT  
20 COULD JUST BE THE LETTER OF ASSURANCE. IT COULD BE AN  
21 EXECUTIVE SUMMARY, OR IT COULD BE ALL THE DATA THAT  
22 WENT INTO THAT ASSURANCE. I THINK THAT WE NEED TO --  
23 THOSE ARE OBVIOUSLY VERY DIFFERENT TYPES OF  
24 INFORMATION.

25 SO I THINK THESE ARE IMPORTANT QUESTIONS THAT

1 I THINK TAKE US TO A LEVEL THAT OUR GROUP HASN'T REALLY  
2 DELVED INTO AND WHICH, AGAIN, THE GRANTS WORKING GROUP  
3 ALSO HAS NOT GOTTEN TO THIS LEVEL OF DEPTH AND  
4 COMPLEXITY.

5 NOW, THE NEXT SLIDE, THERE ARE ISSUES TO  
6 CONSIDER. AND I KNOW WHAT MAKES ALL THIS TOUGH IS  
7 THERE'S NOT JUST ONE ISSUE. I THINK WE START OUT WITH  
8 ACCOUNTABILITY AND TRANSPARENCY ARE REALLY IMPORTANT.  
9 I THINK THIS WORKING GROUP, AND I THINK I SPEAK FOR US  
10 ALL, REALLY STAND BEHIND IN A VERY STRONG FORCEFUL WAY,  
11 THE FACT THAT RESEARCHERS AND INSTITUTIONS SHOULD BE  
12 ACCOUNTABLE AND THAT THE PROCESS OF OVERSIGHT SHOULD BE  
13 TRANSPARENT.

14 NEXT SLIDE, BUT THERE ARE OTHER ISSUES THAT  
15 WE NEED TO KEEP IN MIND. AND ONE IS THAT WHAT IS  
16 REQUIRED FOR OTHER TYPES OF PUBLICLY FUNDED RESEARCH,  
17 AND THERE ARE RULES FOR BOTH RECORDKEEPING AND  
18 DISCLOSURES TO EITHER THE STATE OF CALIFORNIA OR NIH  
19 AND ASSURANCES REQUIRED FOR OTHER PUBLICLY FUNDED  
20 RESEARCH. AND I MEAN HERE NOT JUST THE NIH-FUNDED  
21 RESEARCH, BUT CALIFORNIA ACTUALLY FUNDS RESEARCH ON  
22 TOBACCO, BREAST CANCER, SMOKING CESSATION, A HOST OF  
23 SPECIAL PROGRAMS, WHICH DO HAVE RECORDKEEPING AND  
24 ASSURANCE REQUIREMENTS. I THINK IT WOULD BEHOOVE US TO  
25 SORT OF THINK ABOUT WHAT THOSE PROCEDURES ARE, AND ARE

1     THERE COMPELLING REASONS TO HAVE DIFFERENT REQUIREMENTS  
2     FOR RECORDKEEPING AND ASSURANCE AND PUBLIC DISCLOSURE  
3     IN THIS PARTICULAR TYPE OF RESEARCH.

4             AND FINALLY, I THINK DISCLOSURE AND REPORTING  
5     ARE GOOD, BUT THEY'RE NOT UNLIMITED GOODS OR ABSOLUTE  
6     GOODS.  THERE'S A COST AND THERE'S TIME REQUIRED FOR  
7     REGULATION, REPORTING, AND AUDITING.  AND I MUST SAY  
8     YOU NEED -- WE NEED TO THINK THROUGH SORT OF WHAT OUR  
9     BASIC STRATEGY IS.  AS I TRY TO THINK ABOUT WHAT WE'VE  
10    DONE HERE IN THIS COMMITTEE, ONE OF THE THINGS WE'VE  
11    SAID IS THAT THIS IS A NEW AND DEVELOPING FIELD, AND  
12    THE OVERSIGHT AND REGULATIONS AND GUIDELINES ARE GOING  
13    TO HAVE TO EVOLVE AS WELL.

14            AND THERE'S A LOT OF TIME AND ENERGY THAT WE  
15    WANT TO SEE GO INTO DEVELOPING THE BEST WAYS OF  
16    OVERSIGHT, WORKING OUT SOME OF THE COMPLEXITIES, FOR  
17    INSTANCE, WHAT WE WERE TALKING ABOUT BEFORE THE BREAK,  
18    AND THAT WE ARE COMMITTED, I THINK, TO HELPING  
19    INSTITUTIONS DO THAT BETTER, BUT TRULY USING A QUALITY  
20    IMPROVEMENT MODEL, THAT WE SET THE ISSUE, CHALLENGE  
21    THEM TO THINK OF HOW TO CARRY OUT THOSE GOALS, GET THEM  
22    TALKING TO EACH OTHER AND WITH US AND OTHERS ABOUT HOW  
23    TO DO IT, WHAT WORKS IN DIFFERENT CIRCUMSTANCES, HOW TO  
24    DO IT BETTER.  AND IT'S REALLY A QUALITY IMPROVEMENT  
25    MODEL AS OPPOSED TO A REGULATORY AND AUDITING MODEL.

1                   AND, AGAIN, THOSE WHO ARE FAMILIAR WITH THE  
2                   FEDERAL RESEARCH PROGRAM KNOW THAT OHRP HAS TRIED BOTH  
3                   APPROACHES AND CURRENTLY IS IN A QUALITY IMPROVEMENT  
4                   MODE AS OPPOSED TO A POLICING AND OVERSIGHT MODE. SO I  
5                   THINK THAT WE NEED TO THINK THROUGH WHEN ARE AUDITS  
6                   NECESSARY, WHEN ARE THEY REQUIRED, WHEN MIGHT THEY BE  
7                   UNNEEDED AND ACTUALLY COUNTERPRODUCTIVE IN TERMS OF  
8                   BOTH TIME, ENERGY, AND RESOURCES.

9                   I THINK WE DO HAVE PROVISIONS IN OUR CURRENT  
10                  REGULATIONS THAT CIRM CAN ALWAYS AUDIT ANY INSTITUTION  
11                  IT FUNDS EITHER FOR CAUSE OR ON A RANDOM BASIS SO THAT  
12                  CIRM HAS THE POWER TO REQUIRE ADDITIONAL INFORMATION TO  
13                  ASSURE ITSELF THAT AN INSTITUTION IS IN COMPLIANCE.

14                  WHAT THE COMMENTS WERE DIRECTED TO, I THINK,  
15                  WAS THE NOTION THAT THAT KIND OF AUDITING AND  
16                  INFORMATION ON THE DETAILS OF COMPLIANCE SHOULD BE  
17                  AUTOMATIC AS OPPOSED TO WHEN CALLED FOR. SO THESE ARE  
18                  IMPORTANT ISSUES. I THINK THEY'RE COMPLICATED ISSUES,  
19                  AND I WANT TO AT LEAST GET A START THINKING ABOUT THESE  
20                  ISSUES.

21                  IF I MAY, JOHN SIMPSON IS HERE, AND YOU AND  
22                  OTHERS REALLY WERE THE SORT OF PEOPLE WHO THOUGHT ABOUT  
23                  THIS AND SORT OF PRESENTED IT. YOU WANT TO SAY  
24                  SOMETHING NOW TO KIND OF HELP US GET STARTED, AND I  
25                  KNOW THE COMMITTEE MEMBERS WILL ALSO.

1 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR  
2 TAXPAYER AND CONSUMER RIGHTS. I THINK THE  
3 RECOMMENDATIONS THAT I'VE OFFERED --

4 MR. LOMAX: JUST SORRY TO INTERRUPT YOU.  
5 THERE IS THE ORIGINAL COMMENT IN YOUR PACKET ATTACHED  
6 IN THAT COMPILATION OF LETTERS.

7 MR. SIMPSON: THAT'S EXACTLY WHAT I WAS GOING  
8 TO SAY, THAT IT SHOULD BE IN THE BACK. I REALLY  
9 FOCUSED ON THE ISSUES OF COMPLIANCE AND RECORDKEEPING.  
10 I DIDN'T FOCUS ON MOST OF THE OTHER ISSUES IN THESE  
11 STANDARDS. I'VE ALSO BEEN THINKING A LOT ABOUT  
12 INTELLECTUAL PROPERTY REGULATIONS AND THAT SORT OF  
13 THING, DEALING WITH A LOT OF THAT.

14 CHAIRMAN LO: JOHN, I'M SORRY TO INTERRUPT  
15 YOU. JUST SO YOU KNOW, THE FRONT PAGE LOOKS LIKE THIS,  
16 AND JOHN'S COMMENTS ARE ON PAGE 2, AND THE NEXT PAGE IS  
17 A LONG SET OF COMMENTS THAT'S A COMBINED SET OF  
18 COMMENTS FROM THE PRO-CHOICE ALLIANCE FOR REPRODUCTIVE  
19 RESEARCH AND THE CENTER FOR GENETICS AND SOCIETY.

20 MR. SIMPSON: AND THEY HAVE VERY SIMILAR  
21 COMMENTS AS DO I HAVE. THE SECTION, I BELIEVE, IS  
22 10040 AND 10120. SO IT'S INSTITUTIONAL ASSURANCES AND  
23 COMPLIANCE AND RECORDKEEPING.

24 I GUESS MY THOUGHT ON ALL OF THIS IS THAT  
25 WE'RE GOING DOWN A BRAND NEW ROAD, AND IT'S GOOD TO

1 SPECIFY AS MUCH AS POSSIBLE THE NEED FOR HOW THE  
2 RECORDS ARE GOING TO BE KEPT AND TO TRY AND GET  
3 RESPONSIBILITY AT THE HIGHEST LEVELS. AND THAT'S WHAT  
4 MOST OF THESE ARE ABOUT.

5 WE ALSO, I GUESS, HAVE SOME SKEPTICISM ABOUT  
6 THE POSSIBILITY OF GROUPS ESSENTIALLY WITHIN  
7 INSTITUTIONS TALKING TO THEMSELVES TOO MUCH AND  
8 REINFORCING THINGS. THAT'S WHY WE THINK AN IMPORTANT  
9 PART OF THIS WOULD BE A PROVISION FOR AN OUTSIDE  
10 AUDITOR.

11 AND, AGAIN, WE THINK THAT THE TRANSPARENCY  
12 THAT THIS WORKING GROUP HAS DEMONSTRATED REPEATEDLY IS  
13 ESSENTIAL TO THE WHOLE PROCESS. AND THAT'S WHY A LOT  
14 OF THESE THINGS WERE SUGGESTED SHOULD BE A PUBLIC  
15 RECORD SO THAT IT WOULD MADE AVAILABLE TO THE PUBLIC.

16 THAT'S ESSENTIALLY WHERE I'M COMING FROM. I  
17 DON'T THINK I NEED TO GO OVER EACH PARTICULAR  
18 SUGGESTION, BUT THAT'S ESSENTIALLY OUR PHILOSOPHICAL  
19 COMMENT.

20 CHAIRMAN LO: LET ME HELP TO GET US STARTED.  
21 AS WE LOOK AT SPECIFIC THINGS, I'M SURE YOU WILL WANT  
22 TO COMMENT ON. JUST BECAUSE THESE REALLY ARE A VERY  
23 NICE EXAMPLE OF HOW PUBLIC COMMENT HAS SORT OF PUT  
24 ISSUES BEFORE US THAT RAISED ISSUES THAT REQUIRE US TO  
25 GET INTO SOME GREATER DEPTH. DOES SOMEONE FROM THE

1 PRO-CHOICE ALLIANCE FOR REPRODUCTIVE RESEARCH OR CENTER  
2 FOR GENETICS AND SOCIETY WANT TO MAKE AN OPENING  
3 STATEMENT SO YOU CAN HELP US GET STARTED.

4 MS. GREENFIELD: YEAH, I COMPLETELY AGREE  
5 WITH WHAT JOHN SAID. I'D ALSO LIKE TO SAY IS THE IDEA  
6 THAT IT IS SUCH A NEW FIELD. I THINK THE FOCUS IN OUR  
7 FEELINGS IS THAT IT'S SUCH A NEW FIELD WITH SO MANY  
8 DIFFERENT ETHICAL POSSIBILITIES ARISING. AND IN TERMS  
9 OF LOOKING AT JUST RECENT HISTORY AS WELL, THESE ARE  
10 SOME SUGGESTIONS. THANK YOU.

11 CHAIRMAN LO: COMMENTS FROM THE COMMITTEE?

12 DR. PETERS: BERNIE, I'VE GOT A COUPLE THINGS  
13 THAT I'M THINKING ABOUT HERE WITH REGARD TO THIS  
14 PROPOSAL. I THINK IT'S A GIVEN THAT TRANSPARENCY HAS  
15 BEEN A HIGH VALUE SINCE WE BEGAN. SO THIS IS REALLY A  
16 MATTER OF HOW TO MAKE THINGS TRANSPARENT. IT'S NOT  
17 TURNING THINGS FROM OPAQUE TO BECOMING TRANSPARENT.

18 MY EARS PICKED UP A COMMENT THAT YOU MADE,  
19 BERNIE, ABOUT QUALITY CONTROL. AM I UNDERSTANDING THAT  
20 MAYBE THERE MIGHT BE A RELATIONSHIP BETWEEN ASSURANCE  
21 OF COMPLIANCE ON ONE HAND AND AUDITS THAT WOULD HAVE AS  
22 THE SECOND DUTY ENCOURAGING HIGH QUALITY, WHICH THEN  
23 LEADS ME TO ANOTHER QUESTION. AND WHAT'S THE  
24 RELATIONSHIP BETWEEN MERE COMPLIANCE ON THE ONE HAND  
25 AND WHAT'S HAPPENING WITH THE SCIENCE ON THE OTHER?



1 WOULD THERE BE A CONNECTION BETWEEN THIS AND A FREE  
2 FLOW OF SCIENTIFIC INFORMATION? ARE WE TALKING ABOUT  
3 ALL RECORDS ON THE PART OF A GRANTEE BEING AVAILABLE?  
4 AT WHAT POINT WOULD THIS CONNECT WITH INTELLECTUAL  
5 PROPERTY PROTECTION? OR AM I MAKING SOMETHING MORE  
6 COMPLICATED THAN IT REALLY OUGHT TO BE?

7 MS. LANSING: WE WERE JUST TALKING ABOUT IT,  
8 SO YOU UNDERSTAND WE WERE LISTENING. WE HAVE A QUORUM  
9 NOW, AND WE'RE GOING LOSE IT IN THREE MINUTES. SO  
10 WE'RE QUESTIONING WHETHER WE SHOULD GO BACK AND TRY AND  
11 RESOLVE THINGS WITH A FULL QUORUM, WHICH WILL BE GREAT,  
12 AND ALSO GO BACK TO THE ONE THAT WE HAD TABLED BEFORE  
13 LUNCH, WHICH WAS CORD BLOOD.

14 CHAIRMAN LO: WE HAVE A QUORUM FOR THE NEXT  
15 THREE TO FOUR MINUTES, AND SO WE'RE MADLY TRYING TO SAY  
16 CAN WE TAKE FORMAL VOTES ON THINGS WE'D LEFT AS SENSE  
17 OF THE COMMITTEE. LET'S TRY AND DO THOSE FIRST.  
18 SOMEONE CAN HELP ME GO BACK TO WHAT WE DID JUST A  
19 MINUTE AGO ON CARE FOR COMPLICATIONS OF OOCYTE  
20 DONATION. WE'VE HAD NEW LANGUAGE PROPOSED.

21 MS. LANSING: WHY DON'T YOU GO BACK AND GIVE  
22 US ALL THE STUFF.

23 CHAIRMAN LO: SO THIS, JON AND SHERRY, THIS  
24 IS --

25 MS. LANSING: NO, I KNOW WHAT THIS IS.

1                   CHAIRMAN LO:  SO, JON, THIS IS LANGUAGE ABOUT  
2                   PAYMENT FOR COMPLICATIONS OF -- DIRECT AND PROXIMATE  
3                   COMPLICATIONS OF OOCYTE DONATION AND CIRM-FUNDED  
4                   RESEARCH, TO MAKE IT AVAILABLE AT NO COST TO THE DONOR  
5                   WITH CHANGES TO LEAVE IT UP TO THE INSTITUTION AS TO  
6                   HOW THEY GO ABOUT IT.

7                   MS. LANSING:  OUTSIDE THIRD PARTY.  I'M  
8                   COMFORTABLE WITH THAT.

9                   CHAIRMAN LO:  THE REST OF US VOTED TO ACCEPT,  
10                  BUT WE WERE SHORT A QUORUM.

11                  MR. SHESTACK:  I ACCEPT.  I'M IN FAVOR OF  
12                  THAT.

13                  CHAIRMAN LO:  THAT'S NOW A FORMAL VOTE OF THE  
14                  COMMITTEE.

15                  MS. LANSING:  GO BACK TO THE FIRST TWO.

16                  CHAIRMAN LO:  ALTA, DO YOU WANT TO PROPOSE  
17                  THIS LANGUAGE THAT YOU WORKED ON AT THE BREAK?  WE NOW  
18                  HAVE A QUORUM FOR A MINUTE.

19                  MS. CHARO:  SURE.  SO CAN WE THROW IT UP ON  
20                  THERE?

21                  CHAIRMAN LO:  THIS IS THE ISSUE OF CONSENT  
22                  FOR CORD BLOOD DONATION.

23                  MS. CHARO:  IF NOT, I CAN JUST READ IT OUT.

24                  CHAIRMAN LO:  IT'S NOT ON MY SET.

25                  MS. CHARO:  I E-MAILED IT TO GEOFF.

1 MS. LANSING: TELL ME HOW YOU CHANGED THE  
2 ORIGINAL LANGUAGE.

3 MS. CHARO: GOT RID OF THE WORD "PROGENITOR,"  
4 GOT RID OF TALKING ABOUT THE DONATION AND FOCUSED,  
5 INSTEAD, ON THE MATERIALS THAT CAN BE USED IN THE  
6 CIRM-FUNDED RESEARCH. RETAINED, BECAUSE I WASN'T SURE  
7 WHERE THE POLICY WAS GOING, BUT FOR THE MOMENT WE WERE  
8 KEEPING, I THOUGHT, THE ORIGINAL POLICY OF THE  
9 TWO-PERSON CONSENT. SO BY EXPLICITLY LIMITING IT TO  
10 RESEARCH THAT USES PLACENTA, CORD, OR CORD BLOOD FOR  
11 RESEARCH THAT IS INTENDED TO DERIVE NEW LINES, THUS  
12 GETTING AWAY FROM ANYTHING THAT HAD TO DO WITH  
13 AUTOLOGOUS TREATMENT, THAT WE WOULD ASK -- THERE IT IS.

14 FOR CIRM-FUNDED RESEARCH THAT USES UMBILICAL  
15 CORD, CORD BLOOD, OR PLACENTA AND IS INTENDED TO DERIVE  
16 NEW COVERED STEM CELL LINES FOR USES OTHER THAN  
17 AUTOLOGOUS TREATMENTS, INFORMED CONSENT OF BOTH PERSONS  
18 NAMED ON THE BIRTH CERTIFICATE IS REQUIRED. THE  
19 INFORMED CONSENT SHALL INCLUDE A STATEMENT AS TO  
20 WHETHER THE RESULTING STEM CELL LINES MAY BE AVAILABLE  
21 FOR AUTOLOGOUS TREATMENT IN THE FUTURE.

22 SO THE IDEA WAS TO TRY TO CLEAR AWAY ANY  
23 CONFUSION ABOUT CORD BLOOD OR OTHER MATERIALS THAT ARE  
24 BEING DONATED FOR THE THERAPEUTIC PURPOSES OF  
25 AUTOLOGOUS TRANSPLANT FOR THE NEWBORN OR FOR A NEW

1 RELATIVE ESSENTIALLY, BUT WE UNDERSTAND THAT NOW WE'RE  
2 TALKING ONLY ABOUT THINGS THAT ARE BEING DONATED FOR  
3 RESEARCH PURPOSES TO DEVELOP NEW STEM CELL LINES.  
4 STILL DOWN THE LINE IN THE FUTURE THERE MIGHT BE A  
5 POSSIBILITY OF A THERAPEUTIC USE, BUT THIS FOCUSES ON  
6 THINGS THAT ARE INTENDED FOR RESEARCH PURPOSES.

7 BIRTH -- WHY ARE YOU CONFUSED? WHAT CAN WE  
8 DO?

9 MS. LANSING: EXCUSE ME.

10 MR. SHESTACK: IT'S A WAY OF JUST STATING  
11 WHAT IS KOSHER. IT'S NOT HOW TO KOSHER IT. IT'S NOT  
12 SAYING EVERYONE HAS TO KOSHER IT. IT'S JUST SAYING IF  
13 YOUR FUNDS -- IF YOU'RE CIRM FUNDED, THIS IS WHAT IS  
14 PERMISSIBLE. CORD BLOOD FROM A BANK THAT FOLLOWS THESE  
15 STANDARDS ARE PERMISSIBLE FOR YOU TO USE. SO IT'S SORT  
16 OF SIMPLE IN THAT WAY.

17 MS. CHARO: EXACTLY. CORD BLOOD WILL BE  
18 COLLECTED IN MY MANY DIFFERENT WAYS BY MANY DIFFERENT  
19 PLACES, AND THEY CAN ALL DO WHAT THEY WANT. IF YOU  
20 WANT TO USE MATERIALS FROM THAT BANK OR FROM ANY OTHER  
21 SOURCE OF CORD BLOOD IN YOUR CIRM-FUNDED RESEARCH, WHAT  
22 YOU HAVE TO BE ABLE TO ASSURE IS THAT YOUR MATERIALS  
23 ORIGINALLY CAME ACCOMPANIED BY CONSENT FROM BOTH  
24 PERSONS THAT ARE NAMED ON THE BIRTH CERTIFICATE.

25 MR. SHESTACK: AND THEY KNEW THAT IT WOULD BE

1 CONSENT FOR BLANKET RESEARCH USE OR WHATEVER WAS THEN  
2 BEING AVAILABLE. IN FACT, THAT WOULD WORK.

3 MS. LANSING: JUST LET ME ASK YOU A QUESTION  
4 AS THE LAY PERSON.

5 MS. CHARO: IF IT'S NOT CLEAR, IT SHOULD BE  
6 REWRITTEN.

7 MS. LANSING: SO IN OTHER WORDS, I JUST WANT  
8 TO BE SURE THIS DOESN'T TOUCH IF YOU DON'T KNOW WHO THE  
9 GENETIC PERSON IS FOR AUTOLOGOUS -- FOR THE CHILD.  
10 DOESN'T TOUCH.

11 MS. CHARO: CAN WE SOMEHOW GET THAT THING --

12 MS. LANSING: I KNOW. I SEE THAT. I JUST  
13 WANT TO MAKE SURE.

14 MR. SHESTACK: THIS BASICALLY SAYS YOU GOT TO  
15 HAVE CONSENT FROM BOTH.

16 MS. LANSING: NOT IF JUST FOR YOUR OWN CHILD.

17 MR. SHESTACK: THEN WE WOULDN'T BE --

18 MS. CHARO: SHERRY, WHAT WE MIGHT WANT TO DO  
19 IS ALTER THIS SLIGHTLY AND SAY INFORMED CONSENT OF ALL  
20 PERSONS NAMED ON THE BIRTH CERTIFICATE. THAT COVERS  
21 SITUATIONS WHERE THERE'S ONLY ONE NAMED ON THE BIRTH  
22 CERTIFICATE, WHICH WILL BE A PREDICTABLE KIND OF EVENT,  
23 RIGHT. SO WE'LL CHANGE BOTH TO ALL.

24 MS. LANSING: EXCELLENT. SO INFORMED CONSENT  
25 OF ALL PERSONS ON THE BIRTH CERTIFICATE, WHICH COULD BE

1 JUST ONE, IS REQUIRED.

2 NOW MY QUESTION IS YOU'RE NOT ON THE BIRTH  
3 CERTIFICATE, BUT IT'S YOUR GENETIC MATERIAL.

4 MS. CHARO: CORRECT.

5 MS. LANSING: AND YOU'RE SAYING TO ME WE  
6 DON'T HAVE TO GET THEIR CONSENT?

7 MS. CHARO: YES. THIS IS THE CHOICE WE'RE  
8 BEING FACED WITH, RIGHT. IN A PERFECT WORLD WHERE WE  
9 WANT TO BE COMPLETELY PROTECTIVE OF EACH INDIVIDUAL'S  
10 PRIVILEGE TO REFUSE PARTICIPATION IN RESEARCH AND TO  
11 REFUSE INDIRECT PARTICIPATION IN RESEARCH, WE WOULD BE  
12 ABSOLUTELY INTENT UPON IDENTIFYING THE PATERNAL GENETIC  
13 LINE AND GET THAT GUY'S ACTUAL CONSENT OR REFUSAL.

14 THE COMPROMISE HERE IS TO FOCUS ON THOSE  
15 PERSONS NAMED ON THE BIRTH CERTIFICATE, AND THE  
16 COMPROMISE HERE IS BASED ON THE FOLLOWING. THAT THE  
17 LATEST STUDIES THAT CAME OUT ABOUT TWO WEEKS AGO  
18 SUGGEST THAT ONLY ABOUT 3 TO 7 PERCENT OF THE PATERNITY  
19 ATTRIBUTIONS ARE MISTAKEN, SO BIRTH CERTIFICATE NAMES  
20 ARE A NOT PERFECT, BUT REASONABLY GOOD PROXY FOR THE  
21 GENETIC FATHER.

22 SECOND, RIGHT, THAT THIS IS AN AREA IN WHICH  
23 THERE ARE TWO KINDS OF INTERESTS THAT ARE BEING  
24 IMPLICATED, PRIVACY AND CONTROL OVER RESEARCH AND WHERE  
25 THE GENETIC FATHER IS NOT BEING IDENTIFIED, THE PRIVACY

1 INTEREST AT LEAST IS NOT BEING IMPLICATED.

2 THIRD, THAT UNLIKE THE AREA WHERE IT IS A  
3 SPERM DONOR AND AN EMBRYO DONATION, THIS IS NOT AN AREA  
4 THAT IS NEARLY AS MUCH OF A MORAL HOT BUTTON BECAUSE IT  
5 DOESN'T INVOLVE THE DESTRUCTION OF AN EMBRYO, WHICH IS  
6 ONE OF THE THINGS THAT DROVE THE INCREDIBLY SOLICITOUS  
7 ATTITUDE TOWARDS ANONYMOUS SPERM DONORS IN THE AREA OF  
8 IVF EMBRYO DONATION FOR RESEARCH, BUT HERE IT'S JUST  
9 CORD BLOOD. SO THE DEGREE TO WHICH WE'RE LIKELY TO  
10 OFFEND PEOPLE BY THE UNKNOWN USE OF THEIR OFFSPRING'S  
11 BODY MATERIALS IN RESEARCH SEEM TO BE LOWER.

12 AND FINALLY, IN LIGHT OF THE COMMENTS ABOUT  
13 THE POSSIBILITIES FOR CONFUSION AND DISPUTE OVER WHO IS  
14 THE RIGHT PERSON, AGAIN, BIRTH CERTIFICATE, WHICH IS, I  
15 THINK, FRANCINE'S SUGGESTION, SEEMED TO BE A KIND OF  
16 PROXY, A PRACTICAL PROXY, BUT IT'S NOT PERFECT. IT IS  
17 ABSOLUTELY NOT PERFECT.

18 MS. LANSING: CAN I JUST ASK SOME QUESTIONS?  
19 AGAIN, THIS WOULDN'T BOTHER ME PERSONALLY, BUT I'M JUST  
20 TRYING TO SAY -- LET ME JUST GO TO A SPERM DONOR.  
21 MAYBE I DON'T UNDERSTAND THIS AT ALL. IF YOU'RE A  
22 SPERM DONOR, DO YOU SIGN WHEN YOU'RE SPERM DONOR? I  
23 DON'T THINK YOU DO, BUT I'M JUST ASKING. YOUR SPERM  
24 CAN BE USED FOR REPRODUCTION, BUT YOU DON'T SAY THAT  
25 YOUR SPERM CAN BE USED FOR SCIENCE OR DO YOU?

1 DR. OLDEN: I'D LIKE TO ALSO PUT ON THAT AN  
2 OOCYTE DONOR. I'D LIKE FOR PEOPLE TO ANSWER THAT. IS  
3 THERE A RESPONSIBILITY TO CONSENT THAT INDIVIDUAL? I  
4 WOULD SAY THERE IS A RESPONSIBILITY.

5 DR. TAYLOR: I AGREE AND I THINK IN THE PAST,  
6 WE REALLY HAVEN'T HAD THESE OPPORTUNITIES OR ISSUES.  
7 BUT CLEARLY AT UC SAN FRANCISCO, WE HAVE SPECIFIED THAT  
8 BOTH SPERM AND EGG DONORS NEED TO CONSENT UP FRONT FOR  
9 THE USE OF THOSE MATERIALS IN A KIND OF NONREPRODUCTIVE  
10 WAY. AND SO I THINK THAT THAT'S GOING FORWARD.

11 MS. LANSING: HERE'S WHAT, I GUESS, I'M  
12 SAYING. I KEEP COMING BACK TO THE SAME THING. ALTA, I  
13 SO RESPECT WHAT YOU'RE TRYING TO DO. I GUESS WHAT I'M  
14 SAYING IS WE HAD THIS ORIGINAL LANGUAGE WHICH PROTECTED  
15 THE SPERM DONOR, PROTECTED THE OOCYTE DONOR, MAYBE CUT  
16 US OUT OF SOME RESEARCH, BUT AT THIS POINT LEFT US  
17 PLENTY OF PEOPLE TO DO RESEARCH WITH AND DIDN'T LEAVE  
18 SOMEBODY SAYING, "WAIT A MINUTE. I GAVE MY SPERM OR I  
19 GAVE MY EGG. I HAD NO IDEA THAT YOU WERE GOING TO" --

20 MS. CHARO: THIS ISN'T ABOUT SPERM AND OOCYTE  
21 DONORS WHOSE EMBRYOS ARE NOW BEING REDIRECTED INTO  
22 RESEARCH. THIS IS ABOUT CORD BLOOD AND PLACENTAL  
23 MATERIAL FROM A NEWBORN, SO IT'S A DIFFERENT SITUATION.

24 MS. LANSING: BUT YOUR SPERM IS WHAT GAVE  
25 ME --



1 DR. PRIETO: THERE COULD CONCEIVABLY BE AN  
2 OOCYTE DONOR AND A SPERM DONOR INVOLVED IN IN VITRO  
3 FERTILIZATION, NEITHER OF WHICH WOULD BE ON THE BIRTH  
4 CERTIFICATE.

5 MS. CHARO: AGAIN, THIS IS WHY I KEEP ASKING.  
6 IT'S NOT A MATTER OF RESPECT. I'M JUST TRYING TO  
7 FIGURE OUT WHAT EVERYBODY WANTS TO HAVE WRITTEN DOWN.  
8 BUT THE KEY QUESTION HERE IS WHETHER OR NOT WE FEEL  
9 THAT IT IS NECESSARY TO BE AS SOLICITOUS HERE AS WE ARE  
10 IN THE SITUATION WHICH IT INVOLVES AN UNEXPECTED  
11 DIVERSION OF EMBRYOS FROM REPRODUCTIVE OUTCOMES TO  
12 RESEARCH OUTCOMES. THAT'S AN AREA WHERE WE ALL KNEW  
13 THAT LOTS OF PEOPLE HAVE LOTS OF MORAL OBJECTIONS, AND  
14 SO YOU GO TO THE NTH DEGREE TO GET CONSENT BEFORE IT  
15 HAPPENED. HERE THERE'S NO DESTRUCTION OF AN EMBRYO.  
16 THE ONLY THING THAT'S GOING ON IS THAT CORD BLOOD IS  
17 BEING COLLECTED FOR RESEARCH PURPOSES.

18 DR. PRIETO: IT MAY BE CREATING CELL LINES  
19 WHICH WOULD GO FORWARD AND BE SUITABLE FOR  
20 TRANSPLANTATION CARRYING YOUR GENETIC MATERIAL.

21 MS. CHARO: TO THE EXTENT THAT THAT'S A  
22 PRIVACY ISSUE, IF YOU'RE UNKNOWN, THEN YOUR PRIVACY  
23 CAN'T BE IMPLICATED IN THE USE OF THAT STEM CELL LINE.

24 MS. LANSING: BUT IT MAY NOT BE YOUR WISH.  
25 IT MAY NOT BE WHAT YOU THOUGHT YOU GAVE IT FOR.

1                   MR. SHESTACK: I'M SURE THERE'S A VERY CLEAR  
2 LEGAL OPINION. THE OOCYTE DONOR DOESN'T HAVE ANY  
3 CHOICE IN WHAT PRIVATE SCHOOL THE KID GOES TO  
4 AFTERWARDS. ONCE YOU'VE MADE THE DONATION, YOU HAVE  
5 GIVEN UP YOUR RIGHTS IN THAT.

6                   MS. CHARO: EVEN MORE -- ANOTHER THING JUST  
7 TO KEEP IN MIND AS WE'RE LOOKING FOR ANALOGIES. MOST  
8 OF US HAVE LEFT TISSUE SAMPLES SOMEWHERE. THERE ARE  
9 PATHOLOGY LABORATORIES AND HOSPITALS THAT HAVE TISSUE  
10 SAMPLES ALL OVER THE COUNTRY. THE CURRENT REGULATORY  
11 STANCE IS THAT THOSE TISSUE SAMPLES ARE AVAILABLE FOR  
12 RESEARCH USES WITHOUT OUR INDIVIDUAL PERMISSION UNLESS  
13 WE ARE IDENTIFIABLE AS THE INDIVIDUALS FROM WHOM THE  
14 TISSUE CAME, RIGHT, AND THE RESEARCH POSES MORE THAN A  
15 MINIMAL RISK. THAT'S THE CURRENT REGULATORY STANCE.

16                   SO THAT THE QUESTION HERE IS WHETHER WE WANT  
17 TO GO BEYOND THE KIND OF CURRENT REGULATORY POSITION  
18 WITH REGARD TO TISSUE DONATION AND OTHER CONTEXTS. WE  
19 MAY WELL, BUT I JUST WANT TO MAKE SURE PEOPLE  
20 UNDERSTAND THAT THE BACKGROUND IS NOT ONE OF ABSOLUTE  
21 CONTROL OVER ONE'S BODY TISSUES, LET ALONE TISSUES OF  
22 ONE'S OFFSPRING.

23                   MS. LANSING: BUT WE -- I KEEP SAYING THIS,  
24 AND I SOUND LIKE A BROKEN RECORD. WE ARE GOING INTO  
25 UNKNOWN TERRITORY. AND BECAUSE WE'RE GOING INTO

1 UNKNOWN TERRITORY AND BECAUSE WE CAN STILL DO OUR  
2 RESEARCH WITH THIS MORE STRINGENT LANGUAGE, WHICH WAS  
3 THE ORIGINAL LANGUAGE, I WOULD AT LEAST FEEL MORE  
4 COMFORTABLE STARTING OUT WITH THIS AND THEN REVISITING  
5 IT OVER THE NEXT SEVERAL MONTHS RATHER THAN RUSHING  
6 INTO IT BECAUSE I STILL HAVE SO MANY QUESTIONS.

7 I JUST KEEP SEEING THE POTENTIAL FOR SOMEBODY  
8 SAYING THIS ISN'T WHAT I WANTED AND I'M SUING YOU. AND  
9 THEN I SAY TO MYSELF, MAN --

10 MR. SHESTACK: THE ISSUE -- THE LANGUAGE YOU  
11 WANT TO KEEP IS THE WORD "PROGENITOR."

12 MS. LANSING: I WANT TO KEEP THE ORIGINAL  
13 LANGUAGE, PERIOD.

14 MR. SHESTACK: THE ORIGINAL LANGUAGE  
15 ACTUALLY -- BY KEEPING THE WORD "PROGENITOR," THAT'S  
16 WHAT YOU ARE TRYING TO KEEP.

17 MS. LANSING: WELL, IT'S THE WHOLE THING.  
18 IT'S BASICALLY CLEAN AND SIMPLE, AND IT IS MORE  
19 RESTRICTIVE, AND I STILL THINK THERE'S ENOUGH THERE TO  
20 DO THE RESEARCH. AND I JUST THINK THAT AT THIS --  
21 AGAIN, I SAY AT THIS, AT THIS PARTICULAR TIME AS OUR  
22 BASIC THING GOING FORWARD, I WOULD GO WITH THE STRICTER  
23 THING JUST BECAUSE IT'S SAFE.

24 MS. CHARO: ALL RIGHT. SO HERE'S THE  
25 QUESTION, SHERRY. LET'S ASSUME WHAT WE WANT TO DO IS

1 GO BACK AND LET'S JUST SAY GENETIC FATHER FOR THE  
2 MOMENT. SO YOU WANT TO MAKE SURE THAT THE TISSUE IS  
3 USED ONLY WHEN YOU'VE GOT CONSENT FROM THE GENETIC  
4 MOTHER AND THE GENETIC FATHER. SO NOW WE'RE GOING TO  
5 HAVE TO ASK HOW ARE WE GOING TO IMAGINE THE  
6 CONFIRMATION OF GENETIC PARENTAGE TO TAKE PLACE FOR  
7 BOTH THE MOTHER AND THE FATHER NOW SINCE YOU CAN HAVE  
8 OOCYTE DONATION, YOU CAN HAVE SPERM DONATION, YOU CAN  
9 HAVE ADULTERY, YOU CAN HAVE SEX OUTSIDE OF ALL MARRIAGE  
10 ARRANGEMENTS. SO WHAT IS THE MECHANISM BY WHICH WE  
11 IMAGINE INSTITUTIONS BEING ABLE TO COMFORTABLY FEEL  
12 THAT THEY ARE COMPLYING WITH THE GOAL SET OUT IN THE  
13 REGULATION?

14 DR. KIESSLING: THAT'S GOING TO BE UP TO  
15 THEM. THE CONCERN HERE IS IF THIS OVERRESTRICTION  
16 LEAVES YOU WITH NO STEM CELL LINES TO USE, THEN IT  
17 NEEDS TO BE REVISITED. BUT RIGHT NOW IF YOU WANT TO DO  
18 THE RESEARCH ACCORDING TO WHAT THE MOST CONSERVATIVE  
19 VIEW IS, THAT'S WHAT IT WILL READ.

20 DR. PRIETO: THE CURRENT LANGUAGE ALSO --

21 DR. KIESSLING: YOU HAVE TO HAVE THE GENETIC  
22 MOTHER AND THE GENETIC FATHER'S CONSENT.

23 DR. OLDEN: LET ME SAY I LIKE THE POSITION  
24 THAT SHERRY ARTICULATED AS WELL. AND I DON'T THINK  
25 WE'RE GOING TO, UNLESS WE ACCEPT THE MORE CONSERVATIVE

1 LANGUAGE THAT WAS IN THE ORIGINAL, WE'RE NOT GOING TO  
2 RESOLVE THIS ISSUE BECAUSE I AM ALSO UNCOMFORTABLE WITH  
3 WHAT YOU HAVE ON THE BOARD.

4 MR. SHESTACK: WHAT IS IT THAT YOU -- WHOSE  
5 CONSENT ARE YOU CONCERNED WITH ESTABLISHING IN THIS  
6 CHAIN, JUST SO I UNDERSTAND?

7 DR. OLDEN: WELL, THE LANGUAGE AS IT'S IN THE  
8 ORIGINAL, IT SAYS YOU HAVE TO CONTACT BOTH BIOLOGICAL  
9 PARENTS. AND I WOULD SAY ABOUT THE OOCYTE DONOR, THAT  
10 PERSON SHOULD BE CONTACTED TOO AND CONSENTED. SO I'M  
11 VERY UNCOMFORTABLE.

12 MR. SHESTACK: IF A PREGNANCY THAT DERIVES  
13 FROM AN OOCYTE DONATION EVEN THOUGH THE WOMAN CARRYING  
14 THE --

15 DR. OLDEN: DOES NOT HAVE THE RIGHT TO WAIVE  
16 THE RIGHT OF THE OOCYTE.

17 MS. LANSING: BUT NOT -- BUT NOT FOR THE  
18 OFFSPRING OF THE CHILD. THAT CHILD, HE CAN DO ANYTHING  
19 HE WANTS.

20 DR. OLDEN: ANYTHING HE WANTS TO.

21 MR. SHESTACK: EXCEPT A CORD BLOOD DONATION.

22 DR. OLDEN: RIGHT.

23 CHAIRMAN LO: NO. NO. DONATION FOR THIS  
24 RESEARCH.

25 DR. OLDEN: THESE ARE FOR THE CORD BLOOD

1 DONATION.

2 CHAIRMAN LO: BUT YOU CAN DONATE CORD BLOOD  
3 FOR AUTOLOGOUS TRANSFUSION, STEM CELL BANK FOR OTHER  
4 RESEARCH, BUT YOU CAN'T DONATE FOR DERIVATION OF A NEW  
5 STEM CELL LINE.

6 DR. OLDEN: EXACTLY.

7 MS. CHARO: SHERRY, ONE THING, I WANT TO JUST  
8 POINT OUT THAT THE LANGUAGE THAT'S UP HERE WAS AN  
9 ATTEMPT TO ACTUALLY CAPTURE THE CONSERVATIVE POSITION  
10 BECAUSE THE LESS CONSERVATIVE THAT WAS ON THE TABLE WAS  
11 ELIMINATING CONSENT FROM ANYBODY BUT THE BIRTH MOTHER.

12 MS. LANSING: BIG MISTAKE --

13 MS. CHARO: IF I'M HEARING, I THINK ARE WE IN  
14 DISPUTE OR CONSENSUS OVER WHETHER OR NOT WE WANT TO BE  
15 INSISTENT THAT WE GET TO EVERY GENETIC PARENT OF THE  
16 NEWBORN FOR CONSENT?

17 MS. LANSING: ONLY FOR THIS ONE THING.

18 MR. SHESTACK: I CAN TELL YOU IN ADVANCE  
19 I WILL ABSTAIN. I THINK IT IS -- I DON'T UNDERSTAND  
20 ACTUALLY THE LEGAL OR ETHICAL PRINCIPLE THAT GIVES THE  
21 OOCYTE DONOR FOR THE NEW MOTHER, FOR THE PERSON WHO  
22 WILL END UP HAVING RESPONSIBILITY FOR THAT CHILD,  
23 RIGHTS ON ANY ISSUE ACTUALLY.

24 DR. OLDEN: IT'S A GENETIC PRIVACY ISSUE.

25 MR. SHESTACK: IT'S NOT A PRIVACY ISSUE.

1 PRIVACY IS ALREADY THAT ALL THESE THINGS ANONYMIZED AND  
2 CODED, THAT IT ISN'T A PRIVACY ISSUE.

3 MS. CHARO: MAY I ASK, IF PRIVACY IS THE MAIN  
4 CONCERN, RATHER THAN CONTROL OVER DOWNSTREAM USES OF  
5 YOUR EARLIER ACTIONS, WOULD IT MAKE SENSE TO IDENTIFY  
6 THE PARENTS, THE PEOPLE THAT ARE LISTED ON THE BIRTH  
7 CERTIFICATE, AS WELL AS ANY KNOWN OR ANY IDENTIFIED  
8 GENETIC PARENT? WOULD THAT SATISFY BECAUSE IT'S THE  
9 LINKING OF THE IDENTITY OF THE GENETIC PARENT WITH THE  
10 GENETIC INFORMATION THAT CREATES THE PRIVACY CONCERN.  
11 IF THE GENETIC PARENT IS UNKNOWN OR UNIDENTIFIABLE,  
12 THAT PERSON'S PRIVACY CAN'T BE INVADED BECAUSE THERE'S  
13 NO WAY TO LINK THEM TO THE INFORMATION. IS IT THE  
14 KNOWN PARENT THAT WE WANT TO MAKE SURE IS INCLUDED?

15 DR. OLDEN: LET ME ASK YOU WHAT PERCENTAGE,  
16 AND I DON'T KNOW THIS, OF CHILDREN WHO ARE BORN OUT OF  
17 WEDLOCK, BOTH PARENTS ARE LISTED ON THE BIRTH  
18 CERTIFICATE. MY GUESS IS IT'S LOW. AND LET'S SAY TWO  
19 WEEKS LATER THE PARENT IS IDENTIFIED FOR WHATEVER  
20 REASONS OR TWO YEARS LATER, AND THAT PERSON'S GENETICS  
21 HAS BEEN USED IN STEM CELL. SO FIRST OF ALL, WHAT  
22 PERCENTAGE OF PARENTS, BOTH PARENTS, ARE LISTED ON  
23 BIRTH CERTIFICATES ON OUT-OF-WEDLOCK BIRTHS? MY GUESS  
24 IS IT'S LOW.

25 DR. PRIETO: I THINK THERE'S A PRINCIPLE

1       THERE ALSO THAT IF YOU CHOOSE NOT TO BE IDENTIFIED AND  
2       CHOOSE NOT TO BE INVOLVED, YOU'VE SURRENDERED CERTAIN  
3       RIGHTS THAT YOU HAD THE OPTION OF EXERCISING.

4                 DR. OLDEN:  IF YOU CHOOSE.

5                 DR. PRIETO:  YOU DID CHOOSE BY CHOOSING NOT  
6       TO BE IDENTIFIED, AND YOU DID NOT ELECT TO BE INVOLVED.

7                 MS. LANSING:  YOU MIGHT NOT KNOW.

8                 MR. SHEEHY:  CALIFORNIA, HAVING BEEN THROUGH  
9       THIS PROCESS, CALIFORNIA LAW TENDS TO IMPLY THAT, YOU  
10      KNOW, THAT THERE'S A CERTAIN RESPONSIBILITY, IF YOU ARE  
11      GOING AROUND HAVING SEX WITH PEOPLE, TO FOLLOW UP.  AND  
12      YOU ARE DE FACTO MAKING A CHOICE IF YOU DON'T FOLLOW  
13      UP.  I MEAN TO IMPLY RIGHTS, PARENTAL RIGHTS, IN THIS  
14      WAY KIND OF SCARES ME AS AN ADOPTIVE PARENT.  I JUST  
15      TELL YOU IT KIND OF --

16                DR. OLDEN:  I'M AN ADOPTIVE PARENT AS WELL.

17                MR. SHEEHY:  I'M NOT SURE I UNDERSTAND THE  
18      DEBATE COMPLETELY, BUT --

19                MS. LANSING:  I'M GETTING RATHER CONFUSED  
20      MYSELF NOW.  SO LET'S JUST BE VERY SPECIFIC.

21                DR. PRIETO:  I THINK THERE'S AN IMPORTANT  
22      SOUND PRINCIPLE THERE, THAT WE SHOULD ALLOW PEOPLE TO  
23      EXERCISE THEIR RIGHTS, BUT THAT WE ALSO ALLOW THEM TO  
24      NOT EXERCISE THEIR RIGHTS.  AND IF YOU SURRENDER THEM  
25      BY ACTS OF OMISSION OR ACTS OF COMISSION, THEN YOU'VE



1 GIVEN THEM AWAY. SO BE IT.

2 CHAIRMAN LO: LET ME AGAIN -- ALTA KEEPS  
3 ASKING THE TOUGH QUESTION. SO WHAT ARE WE TRYING TO  
4 PROTECT WITH THIS? I THINK IT REALLY HAS TO DO WITH  
5 NOT DOING THINGS WITH PEOPLE'S TISSUES THAT THEY DIDN'T  
6 KNOW ABOUT OR AGREE TO WHEN IT'S PARTICULARLY  
7 SENSITIVE. AND SO ALTA IS RIGHT, THAT DESTROYING AN  
8 EMBRYO IS EVEN MORE SENSITIVE THAN JUST USING CORD  
9 BLOOD AND PLACENTA FOR STEM CELL RESEARCH. IT'S WHAT  
10 COMES AFTER THAT STEM CELL RESEARCH.

11 RIGHT BEFORE THIS WE WERE TALKING ABOUT  
12 TRANSPLANTING NEURAL STEM CELLS INTO MICE. THERE'S  
13 SOME PEOPLE WHO FIND THAT PROFOUNDLY OBJECTIONABLE AND  
14 WOULD SAY IN NO WAY WOULD I WANT ANY OF MY DNA GOING TO  
15 THAT EXPERIMENT. SO I THINK THAT GIVEN SORT OF THE  
16 UNKNOWN NATURE OF FUTURE STEM CELL RESEARCH, WHAT WE'VE  
17 SAID BEFORE IS THAT YOU'VE GOT TO CONSENT THAT THINGS  
18 ARE GOING TO BE DONE WITH YOUR MATERIAL THAT WE REALLY  
19 CAN'T DESCRIBE, BUT YOU'VE GOT TO TRUST US TO GO  
20 THROUGH SCIENTIFIC REVIEW AND ETHICS REVIEW. AND IF  
21 YOU'RE NOT COMFORTABLE WITH US, THAT'S FINE. WE  
22 RESPECT THAT. BUT WE DON'T WANT TO HAVE RESEARCHERS  
23 USING MATERIALS ONLY TO FIND THAT FURTHER DOWN THE ROAD  
24 THEY CAN'T DO THE NEXT KEY EXPERIMENT AND HAVE TO START  
25 ALL OVER AGAIN.

1 I JUST THINK THAT I REALLY AGREE WITH WHAT  
2 SHERRY IS SAYING. GIVEN WHERE WE ARE NOW, WE'RE JUST  
3 STARTING OUT, TRYING TO BUILD PUBLIC TRUST, IF WE DON'T  
4 DO THINGS WITHOUT PEOPLE'S EXPLICIT CONSENT, THAT'S A  
5 SOLID POSITION. AND AGAIN, WE DON'T TAKE MATERIALS  
6 AFTER PEOPLE DIE FOR TRANSPLANTATION. AND PEOPLE HAVE  
7 GOTTEN VERY UPSET UNDER THE ANONYMIZED, WE'RE GOING TO  
8 USE IT, IT'S GOING TO BE THROWN OUT, IT'S MATERIALS  
9 WE'RE GOING TO USE FOR RESEARCH WITHOUT TELLING YOU.  
10 THE HENRIETTA LACKS FAMILY WAS VERY UPSET WHEN THEY  
11 FOUND OUT THAT HER MATERIALS WERE USED FOR RESEARCH,  
12 VERY VALUABLE RESEARCH, VERY GOOD RESEARCH, BUT THEY  
13 WEREN'T TOLD. THEY WEREN'T ASKED. AND THE FACT THAT  
14 YOU ANONYMIZE IT AT THE ONSET DOESN'T TAKE AWAY THAT  
15 STING THAT YOU DID IT WITHOUT TELLING ME.

16 MS. LANSING: AND I CAN'T TELL YOU I COME  
17 BACK TO WHERE I WAS, AND I REALLY AM NOW CLEAR. WHY  
18 DON'T WE JUST DO IT THIS WAY, AND THEN SEE IN SIX  
19 MONTHS HOW MUCH IT'S AFFECTING US. AND IF WE'RE NOT  
20 GETTING ENOUGH CORD BLOOD, THEN WE CAN DEAL WITH IT  
21 AGAIN. WE CAN COME BACK AND SAY, YOU KNOW, THIS HAS  
22 REALLY IMPINGED OUR ABILITY TO GET THE RESEARCH THAT WE  
23 NEED, AND WE'RE MAKING THE CHANGE.

24 DR. PRIETO: SHERRY, COULD I JUST ADD, COULD  
25 WE ADD AFTER PLACENTA ALTA'S LINE FOR USES OTHER

1 THAN -- IF WE TOOK THE ORIGINAL LANGUAGE AND ADDED FOR  
2 USES OTHER THAN AUTOLOGOUS TREATMENTS, BECAUSE CLEARLY  
3 THAT'S, YOU KNOW, THERE'S NO NEED TO CONSENT OTHER THAN  
4 THE MOTHER OR GUARDIAN FOR THAT. AND AS IT'S CURRENTLY  
5 WRITTEN, AS THE ORIGINAL LANGUAGE STATES, CONSENT SHALL  
6 BE OBTAINED FOR EACH KNOWN LEGAL PARENT, GUARDIAN, OR  
7 PROGENITOR, I THINK AUTOMATICALLY EXCLUDES THOSE  
8 PERSONS WHO CHOOSE NOT TO BE KNOWN.

9 MS. LANSING: THAT'S WHAT IT SAID IN THE  
10 ORIGINAL LANGUAGE.

11 DR. PRIETO: YES, THAT'S THE ORIGINAL  
12 LANGUAGE. BY OMISSION OR COMMISSION, IF THEY HAVE  
13 CHOSEN NOT TO BE KNOWN, THEY'VE SURRENDERED THAT RIGHT.  
14 I'M FINE WITH THAT.

15 DR. OLDEN: I ALSO CAUTION THAT THE GROUP  
16 THAT WOULD BE MOST AFFECTED BY THE LANGUAGE AS YOU HAVE  
17 IT UP THERE, ALTA, WOULD BE RACIAL AND  
18 SOCIOECONOMICALLY DISADVANTAGED POPULATIONS. SO I  
19 THINK, AGAIN, THAT WOULD BE ANOTHER REASON FOR CAUTION  
20 HERE.

21 MS. LANSING: THE ORIGINAL LANGUAGE SAYS FOR  
22 EACH KNOWN, SO THAT TAKES CARE OF THE --

23 DR. KIESSLING: DR. OLDEN, WHAT LANGUAGE  
24 WOULD MAKE YOU MOST COMFORTABLE?

25 DR. OLDEN: THE ORIGINAL LANGUAGE THAT IS THE

1 MOST CONSERVATIVE.

2 DR. KIESSLING: THAT'S GOT THE WORD  
3 "PROGENITOR" IN IT.

4 DR. OLDEN: WELL, WE CAN TAKE THAT WORD OUT.

5 MS. CHARO: IT ALSO HAS THE WORD "KNOWN" IN  
6 IT. YOU'VE MADE THE POINT SOMEBODY CAN COME BACK TWO,  
7 THREE YEARS LATER. SO ARE YOU COMFORTABLE WITH THE  
8 LANGUAGE --

9 DR. OLDEN: I'M COMFORTABLE WITH WHAT YOU  
10 HAVE UP HERE. I'M COMFORTABLE WITH YOUR REWRITE WITH  
11 ONE EXCEPTION, AND THAT IS THE NAMES ON THE BIRTH  
12 CERTIFICATE. IF THAT WAS NOT ON THERE, I WOULD BE  
13 COMFORTABLE WITH THAT.

14 DR. KIESSLING: WHAT YOU'RE AFTER IS USING  
15 ONLY LINES THAT HAVE TWO GENETICALLY IDENTIFIED PARENTS  
16 AND THEY BOTH GAVE THEIR CONSENT.

17 DR. OLDEN: RIGHT.

18 DR. KIESSLING: THAT'S YOUR BIGGEST COMFORT  
19 ZONE. THE ORIGINAL LANGUAGE DOESN'T DO THAT.

20 MR. SHESTACK: IT DOESN'T. IT ACTUALLY SETS  
21 UP A CLASS OF -- BY SAYING PROGENITOR, IT JUST SETS UP  
22 A POTENTIAL SUBCLASS OF DONORS WHOSE BIRTH RESULTED  
23 FROM AN OOCYTE DONATION. IF YOU WANT TO JUST SAY  
24 SIMPLY TO BE ULTRA KOSHER ABOUT THIS, JUST GOING TO SAY  
25 YOU CAN TAKE AND USE CORD BLOOD FROM SITUATIONS WHERE

1 YOU HAVE, LIKE, STANDARD BIOLOGICAL BIRTH, TWO PARENTS,  
2 NO OTHER DONORS, WE KNOW EXACTLY WHO EVERYONE IS. JUST  
3 DO THAT, MAKES IT SIMPLER.

4 MS. LANSING: I'M COMFORTABLE WITH THE  
5 ORIGINAL LANGUAGE, WHICH SAYS FOR EACH KNOWN LEGAL  
6 PARENT, GUARDIAN, OR PROGENITOR. I MEAN, YOU KNOW --

7 DR. OLDEN: I AM TOO. I'M COMFORTABLE WITH  
8 THAT.

9 MS. CHARO: IF I MAY, THOUGH, I'M STILL  
10 CONFUSED BECAUSE I THOUGHT THAT YOU WERE MAKING A POINT  
11 EARLIER, DR. OLDEN, THAT WE DON'T KNOW WHO THESE PEOPLE  
12 ARE AND THEY MAY COME FORWARD LATER, AND WE WANT TO  
13 ACCOMMODATE THAT.

14 DR. OLDEN: THAT'S CORRECT. THEY MAY.

15 MS. CHARO: BUT THE OLD LANGUAGE DOESN'T  
16 HANDLE THAT SITUATION.

17 DR. OLDEN: BUT THE OLDER LANGUAGE IS BETTER.  
18 I'M MORE COMFORTABLE WITH THE OLDER LANGUAGE THAN  
19 ANYTHING I'VE HEARD.

20 MS. CHARO: ALL RIGHT. SO YOU THINK IT'S  
21 BETTER, BUT IT'S STILL NOT PERFECT.

22 DR. OLDEN: WELL, I THINK WE ALL AGREE THAT  
23 WE DON'T HAVE IT PERFECT.

24 MS. CHARO: KNOWN AS OF WHEN? AS OF THE  
25 MOMENT OF DONATION? I'M JUST TRYING TO MAKE SURE IF WE

1 STICK WITH THE OLD LANGUAGE, WE DON'T CREATE PROBLEMS  
2 THAT HAVE BEEN IDENTIFIED TO US.

3 DR. OLDEN: IF YOU PUT UP LANGUAGE THAT I CAN  
4 AGREE WITH, I THINK I CERTAINLY WOULD VOTE IN FAVOR OF  
5 IT.

6 DR. PETERS: KNOWN IS VAGUE. KNOWN BY WHOM  
7 AND WHAT PERIOD OF TIME? THERE'S A SLIGHT ADVANTAGE IN  
8 USING THE BIRTH CERTIFICATE CRITERIA, IT SEEMS TO ME,  
9 BECAUSE HOW MUCH OF A BURDEN ARE WE GOING TO PUT ON THE  
10 RESEARCHERS TRYING TO GET THESE SIGNED CONSENT FORMS TO  
11 DO AN INVESTIGATION? SO IT'S POSSIBLE YOU COULD END UP  
12 THAT THEY'D INVESTIGATE FOUR PEOPLE, THE BIRTH PARENTS  
13 AS WELL AS THE OOCYTE DONOR AND THE SPERM DONOR. DO WE  
14 WANT THEM TO HAVE TO DO ALL THAT?

15 MS. CHARO: RIGHT. IF WE'RE STICKING WITH  
16 THE CONCEPT OF KNOWN GENETIC PARENTS OF THE NEWBORN AS  
17 WELL AS LEGAL PARENTS BECAUSE YOU CAN'T CUT THEM OUT OF  
18 THE CONSENT PROCESS, WE CAN AT LEAST REDUCE SOME OF THE  
19 UNCERTAINTIES THAT TED'S IDENTIFIED BY AT LEAST SAYING  
20 SOMETHING ABOUT KNOWN AT WHAT TIME, RIGHT. SO THAT AT  
21 LEAST RESEARCHERS CAN BE CONFIDENT THAT THEY'VE ASKED  
22 THE RIGHT QUESTIONS AT THE RIGHT TIME.

23 MS. LANSING: LET ME BE EVEN MORE  
24 CONSERVATIVE.

25 DR. PRIETO: THIS IS THE NEW LANGUAGE YOU

1 HAVE UP HERE NOW TO COVER THAT?

2 MS. CHARO: NO. GEOFF IS BEGINNING TO FOOL  
3 WITH IT, BUT IT'S NOT EXACTLY.

4 MS. LANSING: CAN I ASK YOU QUESTION, AGAIN,  
5 AS A LAYPERSON? WHAT IF YOU DID SAY -- LET ME JUST ASK  
6 YOU. THE MOST STRICT WOULD BE THAT YOU CAN'T DO CORD  
7 BLOOD RESEARCH UNLESS YOU KNEW THE GENETIC PARENTS,  
8 RIGHT? THAT WOULD BE THE MOST STRICT. THAT WOULD BE  
9 THAT IF YOU DIDN'T KNOW THEM, YOU COULDN'T DO THE  
10 RESEARCH. THAT'S REALLY GOING EVEN MORE CONSERVATIVE  
11 THAN WHAT THIS SAYS AND PROTECTING POTENTIAL PEOPLE  
12 COMING IN LATER. HOW DAMAGING IS THAT?

13 DR. KIESSLING: THAT'S THE BEST SCIENCE.

14 MS. LANSING: OKAY. GREAT. THAT'S GREAT.  
15 HOW DAMAGING IS -- THAT'S THE BEST SCIENCE.

16 MS. CHARO: HOW ARE YOU GOING TO KNOW WHO THE  
17 GENETIC PARENTS ARE?

18 DR. TAYLOR: ACTUALLY I THINK FROM AN  
19 INVESTIGATOR --

20 MS. LANSING: IF YOU DON'T KNOW --

21 MS. CHARO: HOW CAN YOU EVER KNOW UNTIL YOU  
22 ACTUALLY TEST PEOPLE? ARE YOU SAYING WHAT WE SHOULD DO  
23 IS NOT ACCEPT THE CORD BLOOD UNLESS WE'VE ACTUALLY DONE  
24 A DNA TEST TO CONFIRM GENETIC PARENTAGE? I'M TRYING TO  
25 UNDERSTAND HOW DO YOU KNOW WHO THE GENETIC PARENTS

1 WERE?

2 DR. TAYLOR: AS AN INVESTIGATOR DOING A  
3 PROJECT LIKE THIS, I WOULDN'T WANT TO INVEST THE EFFORT  
4 TO DERIVE A STEM CELL LINE THAT I DIDN'T FEEL I HAD A  
5 REALLY GREAT OPPORTUNITY TO LOOK AT THE TWO PARENTS AND  
6 LOOK FOR FUTURE GENETIC ABNORMALITIES. SO I THINK IT'S  
7 ACTUALLY -- I LIKE THE LANGUAGE BECAUSE THE LANGUAGE  
8 ISN'T SO STRICT, BUT THE REALITY IS THAT FOR AN  
9 INVESTIGATOR TO INVEST THE EFFORT THIS IS GOING TO  
10 REQUIRE, THEY'RE GOING TO WANT TO HAVE A DAMN GOOD IDEA  
11 THAT THESE ARE REALLY THE BIOLOGICAL PARENTS. AND I  
12 THINK IT'S IRRESPONSIBLE OF THEM TO SORT OF PURSUE THIS  
13 WITHOUT HAVING THAT INFORMATION.

14 DR. PRIETO: DOES THIS NEW LANGUAGE CAPTURE  
15 THAT, WHAT'S UP ON THE SCREEN NOW THAT WAS JUST  
16 MODIFIED?

17 MS. CHARO: IT'S NOT EXACTLY WRITTEN TO BE  
18 ADOPTED IN THAT FORM. THAT BLUE PHRASE IS NOT KIND OF  
19 WRITTEN INTO THE SENTENCE.

20 CHAIRMAN LO: WELL, AGAIN, I THINK WE'RE  
21 GOING TO LOSE OUR QUORUM, BUT THIS IS A TOUGH ISSUE. I  
22 GUESS I'M GOING TO PICK UP ON WHAT ROB TAYLOR SAID. I  
23 MEAN DERIVING STEM CELL LINES IS NOT EASY. AND OUR  
24 ULTIMATE GOAL IS TO USE THESE STEM CELL LINES FOR  
25 TRANSPLANTATION FOR CLINICAL CURES AND TREATMENTS. AND



1 IT STRIKES ME THAT IT WOULD BE UNWISE, REGARDLESS OF  
2 WHAT THE FDA REQUIRES, TO TRANSPLANT CELLS INTO A  
3 PERSON, PARTICULARLY IF THERE'S GOING TO BE  
4 IMMUNOSUPPRESSION, WHERE YOU DON'T HAVE SOME SENSE OF  
5 THE GENETIC HISTORY OF THE PEOPLE WHO CONTRIBUTED THE  
6 DNA.

7 I JUST THINK THAT IF THERE'S A FAMILY HISTORY  
8 OF CANCER THAT YOU DID NOT KNOW ABOUT BECAUSE YOU  
9 DIDN'T KNOW WHO THE FATHER WAS OR THE GENETIC MOTHER  
10 WAS --

11 MR. SHESTACK: THAT'S A SCIENTIFIC ISSUE, NOT  
12 AN ETHICAL ISSUE. RESEARCHERS WON'T CHOOSE THOSE CELL  
13 LINES FOR EXACTLY THAT REASON. THAT'S NOT WHAT WE'RE  
14 HERE TO DECIDE.

15 CHAIRMAN LO: RISK TO TRANSPLANT RECIPIENTS.  
16 IT'S AN ETHICAL ISSUE IN TERMS OF USE OF RESOURCES. IF  
17 WE FUND SOMEONE WHO USES A LINE THAT WE THEN CAN'T USE  
18 FOR TRANSPLANTATION, WE'VE GOT TO REDO ALL THAT.

19 DR. OLDEN: YOU CAN'T UNCOUPLE ETHICS FROM  
20 THE QUALITY OF THE SCIENCE. THEY'RE LINKED.

21 DR. PRIETO: CAN I MAKE A SUGGESTION, THAT WE  
22 ACCEPT THE ORIGINAL LANGUAGE WITH TWO MODIFICATIONS.  
23 FOR CIRM-FUNDED RESEARCH INVOLVING THE DONATION OF  
24 UMBILICAL, CORD BLOOD, OR THE PLACENTA FOR PURPOSES  
25 OTHER THAN AUTOLOGOUS TREATMENTS, CONSENT SHALL BE

1 OBTAINED FROM EACH KNOWN LEGAL PARENT, GUARDIAN, OR  
2 IDENTIFIED GENETIC PARENT. THE REMAINDER STAYS THE  
3 SAME.

4 MS. LANSING: I'M COMFORTABLE WITH THAT.  
5 AGAIN, WANT TO PUT A BIG ADDENDUM ON IT AND SAY WE'RE  
6 GOING TO KEEP REVISITING THIS ISSUE, YOU KNOW.

7 DR. PRIETO: IT COVERS SOME OF THE CONCERNS  
8 THAT WERE RAISED TODAY. IT DOESN'T ANSWER ALL  
9 QUESTIONS, WHICH I THINK WE'RE NOT GOING TO ANSWER.

10 MS. LANSING: I THINK THIS IS --

11 DR. PRIETO: CAN I MAKE THAT AS A MOTION?

12 CHAIRMAN LO: CAN I MAKE A FRIENDLY  
13 SUGGESTION, AND THAT'S TO SAY FOR THE PURPOSES OF --  
14 FOR PURPOSES OF STEM CELL DERIVATION, THAT IF IT'S FOR  
15 RESEARCH --

16 MS. LANSING: JON, DON'T LEAVE. WE GOT TO  
17 VOTE ON THIS.

18 MR. SHESTACK: I'M LATE.

19 MS. LANSING: I AM TOO, BUT WE'VE GOT TO VOTE  
20 ON THIS. OTHERWISE, WE CAN'T --

21 DR. PRIETO: FOR PURPOSES OF --

22 CHAIRMAN LO: STEM CELL DERIVATION. RESEARCH  
23 THAT CIRM MAY FUND THAT'S NOT INTENDED FOR STEM CELL.

24 DR. PRIETO: YES, I'D CONSIDER THAT A  
25 FRIENDLY AMENDMENT. CONSENT SHALL BE OBTAINED FROM

1 EACH LEGAL PARENT, GUARDIAN, OR IDENTIFIED GENETIC  
2 PARENT.

3 MS. PASTORE: I THINK YOU WANT "AND" TO  
4 ACCOMPLISH WHAT YOU WANT.

5 MS. LANSING: READ IT BACK.

6 DR. PRIETO: FOR CIRM-FUNDED RESEARCH  
7 INVOLVING THE DONATION OF THE UMBILICAL CORD, CORD  
8 BLOOD, OR THE PLACENTA FOR PURPOSES OF STEM CELL  
9 DERIVATION, CONSENT SHALL BE OBTAINED FROM EACH KNOWN  
10 LEGAL PARENT, GUARDIAN, AND IDENTIFIED GENETIC PARENT.  
11 INFORMED CONSENT SHALL INCLUDE A STATEMENT AS TO  
12 WHETHER THE DONATED CELLS MAY BE AVAILABLE FOR  
13 AUTOLOGOUS TREATMENT IN THE FUTURE.

14 CHAIRMAN LO: WE'RE SAFE.

15 MS. LANSING: OKAY.

16 CHAIRMAN LO: THAT'S BEEN THE MOTION.

17 DR. PRIETO: THAT'S MY MOTION.

18 CHAIRMAN LO: SECOND ON THAT?

19 DR. KIESSLING: I'LL SECOND THAT.

20 CHAIRMAN LO: ALL THOSE IN FAVOR. WHO ELSE  
21 IS ON THE PHONE? ANYONE STILL THERE? JON, YOU'RE A  
22 HERO, BUT UNFORTUNATELY IT WENT FOR NAUGHT. THANK YOU  
23 SO MUCH.

24 MS. LANSING: THANK YOU, JON. SO WHEN WE GO  
25 BACK TO THE FULL ICOC, WE CAN SAY THAT THIS IS THE

1 SENSE, BUT WE AGREED THIS ISN'T PERFECT.

2 MR. SHEEHY: YOU JUST ASKED FOR AYES. I'D  
3 LIKE TO HEAR WHAT THE ACLU'S POSITION IS ON THIS NEW  
4 LANGUAGE BECAUSE I'M STILL -- I'M WORRIED ABOUT THE  
5 INCONSISTENCY WITH EXISTING CALIFORNIA LAW. I WOULD  
6 ABSTAIN IF THEY STILL HAVE A STRONG OBJECTION.

7 CHAIRMAN LO: PUBLIC COMMENT?

8 MS. PASTORE: CLARE PASTORE FROM THE ACLU.  
9 THANK YOU FOR THE OPPORTUNITY TO ADDRESS THAT. I'M  
10 STILL TROUBLED BY LEAVING THIS -- TAKING THIS DECISION  
11 OUT OF THE HANDS OF THE WOMAN WHO OTHERWISE HAS CONTROL  
12 OVER THE PREGNANCY AND THE BIRTH. SO I UNDERSTAND THE  
13 PRINCIPLES, AND CERTAINLY THE ACLU IS VERY CONCERNED  
14 ABOUT PRIVACY IMPLICATIONS IN MEDICAL RESEARCH AND  
15 ELSEWHERE. MY JUDGEMENT IS THAT I WOULD STILL STICK  
16 WITH MY ORIGINAL POSITION, WHICH IS THAT CONSENT SHOULD  
17 BE OBTAINED FROM THE WOMAN.

18 MR. SHEEHY: THIS CAN'T BE HEARD AS A  
19 CONSENSUS.

20 CHAIRMAN LO: WE DON'T HAVE CONSENSUS.

21 MS. LANSING: WE DON'T HAVE A CONSENSUS.

22 WHAT WE HAVE IS --

23 CHAIRMAN LO: WHO'S AN AYE AND NAYS --

24 MS. LANSING: WE DON'T NEED -- I'M GOING TO  
25 LEAVE.

1                   CHAIRMAN LO: I JUST WANTED TO HAVE A SENSE.  
2 WE DON'T HAVE A QUORUM. WE CAN PUT THIS FORTH TO THE  
3 ICOC AS A SENSE OF THE COMMITTEE. I THINK IT WOULD BE  
4 USEFUL TO SAY HOW MANY FAVORED AND HOW MANY OPPOSED.

5                   MS. LANSING: BUT I HAVE A QUESTION JUST  
6 PROCEDURALLY. WHAT HAPPENS, GEOFF, IF WE DON'T HAVE  
7 THE SENSE OF THE COMMITTEE THAT'S POSITIVE? THEN WHAT  
8 HAPPENS TO US IN TERMS OF THIS, IN TERMS OF -- DOES IT  
9 TRIGGER ANYTHING THAT WE HAVE TO START ANOTHER 45-DAY  
10 PERIOD AND CAN'T GIVE --

11                   MR. LOMAX: PERHAPS I'LL DEFER TO SCOTT ON  
12 THAT BECAUSE IT'S -- I THINK THERE'S A LOT OF NUANCE TO  
13 THAT ANSWER.

14                   MR. TOCHER: THE ICOC CAN ONLY ADOPT  
15 REGULATIONS THAT HAVE BEEN DULY NOTICED TO THE PUBLIC.  
16 THE WAY TO ASSURE THAT THERE IS NO PROBLEM AT THE ICOC  
17 MEETING WOULD BE TO, IF THERE REALLY IS NO CONSENSUS,  
18 IS TO AT LEAST FOR THE NEXT 15 DAYS PUBLICLY NOTICE  
19 VARIOUS VERSIONS SO THAT WHEN THE ICOC, IF THERE IS NO  
20 INTERVENING MEETING OF THIS GROUP TO MAKE A  
21 RECOMMENDATION, FORMAL RECOMMENDATION ON ONE PARTICULAR  
22 VERSION, IS TO AT LEAST PROVIDE THE ICOC THE  
23 OPPORTUNITY TO HAVE BEFORE IT THE VARIOUS OPTIONS THAT  
24 THEY MIGHT CONSIDER ADOPTING SO THAT WHEN THEY DO ADOPT  
25 IT, THOSE HAVE BEEN DULY NOTICED UNDER THE OAL.

1 MS. LANSING: SO CAN I PROPOSE SOMETHING?  
2 MAYBE I'M WRONG. I WOULD LIKE TO PROPOSE THAT WE DO  
3 THAT, BUT THAT I WOULD LIKE TO PROPOSE THAT WE DON'T --  
4 WE'RE STILL TALKING, WE'RE STILL LISTENING, AND THAT WE  
5 HAVE AN INTERVENING PHONE CONVERSATION TO SEE IF WE CAN  
6 GET A SENSE OF CONSENSUS AND CONTINUE TO WORK ON  
7 LANGUAGE, WE'LL CONTINUE TO SEE BECAUSE WE STILL -- I  
8 JUST -- I GUESS I JUST DON'T WANT THIS TO BE A SPLIT  
9 VOTE. I ALSO DON'T WANT THIS TO BE SOMETHING THAT  
10 INHIBITS OUR ABILITY TO GIVE OUT THE FUNDING, AND WE  
11 DON'T HAVE THE STANDARDS IN PLACE, AND THEN THAT WOULD  
12 BE TERRIBLE.

13 CHAIRMAN LO: SHERRY, FOR THE SAKE OF  
14 CONVERSATION AND DISCUSSION, IF THE VOTE -- HOW MANY  
15 PEOPLE IN THE ROOM VOTED? NINE. SUPPOSE IT WAS SEVEN  
16 FOR, NO AGAINST, AND TWO ABSTENTIONS? WOULD THAT BE A  
17 SENSE OF THE COMMITTEE YOU COULD FEEL COMFORTABLE WITH?

18 MR. SHEEHY: I PERSONALLY WOULD BE HAPPIEST  
19 IF WE PUBLISHED ALL DIFFERENT VERSIONS. I'D REALLY BE  
20 HAPPY IF WE COULD GET THE ACLU VERSION TO PUBLISH AS  
21 WELL SO THAT WE HAVE THIS ALL OUT THERE, AND ICOC CAN  
22 DO IT. AND, YOU KNOW, YOU CAN MAKE -- THE SAME SENSE  
23 OF URGENCY APPLIES THERE, AND WE WOULD HAVE COMPLIED, I  
24 THINK, WITH SCOTT'S MANDATE THAT WE HAVE IT ALL  
25 PUBLICLY AVAILABLE. WE'LL HAVE THE VERSIONS THERE, AND

1       WHATEVER VOTE TAKES PLACE AT THE ICOC --

2                   MS. LANSING:  IS THAT GOOD ENOUGH, SCOTT?  IF  
3       ALL THE VERSIONS GO OUT WITHOUT AN INTERVENING PHONE  
4       CALL, AND THEN THE ICOC ADDRESSES IT AS A MATTER THAT  
5       THEY HAVE A GREAT DEAL OF URGENCY FOR AND IT WILL NOT  
6       START THE CLOCK TICKING AGAIN?

7                   MR. TOCHER:  RIGHT.  SO LONG AS THE LANGUAGE,  
8       WHATEVER LANGUAGE IS ADOPTED HAS BEEN DULY NOTICED.  
9       THAT'S THE TEST.

10                  CHAIRMAN LO:  HOW LONG DOES THAT TAKE?

11                  DR. PRIETO:  AND AVAILABLE FOR COMMENT.

12                  MR. TOCHER:  AND AVAILABLE FOR COMMENT, WHICH  
13       MEANS FROM THIS POINT, THERE WILL BE AN ADDITIONAL  
14       15-DAY COMMENT PERIOD BECAUSE THIS IS ALL --

15                  CHAIRMAN LO:  AFTER THE ICOC.

16                  MR. TOCHER:  NO.  AFTER THIS MEETING.

17                  MS. LANSING:  WHEN DO WE MEET?

18                  MR. TOCHER:  JUNE 2D, IT'S A FRIDAY.

19                  CHAIRMAN LO:  SO YOU COULD NOTICE THIS  
20       WHENEVER --

21                  MR. TOCHER:  IT WOULD NEED TO BE POSTED BY  
22       MAY 18TH, WHICH WILL BE THE VERY LAST DAY, BUT  
23       PRESUMABLY IF WE POST IT BY FRIDAY, MAY 5TH, OR  
24       FOLLOWING ON THE 12TH, POST IT ON OUR WEBSITE, A NEW  
25       15-DAY COMMENT PERIOD, COMMENT WOULD BE RECEIVED AND

1 DIGESTED IN TIME FOR THE ICOC MEETING.

2 MS. LANSING: SO THEN I'D LIKE TO MAKE  
3 ANOTHER SUGGESTION. MAY 5TH IS THIS FRIDAY. IT'S LIKE  
4 TWO DAYS AWAY. WE HAVE A LOT OF OTHER STUFF TO GO  
5 THROUGH. WE'RE GOING TO BREAK FOR LUNCH ANY SECOND.  
6 WHY DON'T WE KEEP WORKING. WE DON'T HAVE A QUORUM  
7 ANYWAY. AND WHY DON'T WE SEE IF WE CAN COME UP WITH  
8 SOMETHING THAT MAKES EVERYBODY HAPPY, COME BACK TO IT.  
9 WE DON'T HAVE A QUORUM. COME BACK TO IT, A SENSE OF  
10 THE COMMITTEE, AND POST THAT AS WELL. IF WE CAN'T, WE  
11 CAN'T.

12 DR. TAYLOR: I WOULD ARGUE THAT WE'RE NOT  
13 GOING TO GET THERE, AND THAT THIS POSTING IS ACTUALLY  
14 GOING TO BE MUCH MORE EXPEDITIOUS. FROM THE  
15 CONVERSATION, I JUST DON'T SEE A CONSENSUS ARISING NO  
16 MATTER HOW WE DIDDLE WITH THE LANGUAGE.

17 MS. CHARO: I THINK WE NOW HAVE THREE THAT  
18 REPRESENT THE THREE DIFFERENT VERSIONS.

19 CHAIRMAN LO: LET ME MAKE A SUGGESTION. I  
20 THINK THIS IS IMPORTANT, AND THERE ARE OTHER IMPORTANT  
21 THINGS, AND WE SORT OF TABLED SOME IMPORTANT ISSUES. I  
22 SUGGEST THAT WE NOT TRY AND SETTLE THIS NOW. WE SAVE  
23 SOME TIME BEFORE WE ADJOURN TO AT LEAST LOOK AT THE  
24 THREE VERSIONS, SEE IF WE CAN REACH CONSENSUS ON ANY  
25 ONE OF THEM. IF NOT, THEN WE WOULD POST IT, NOTICE IT.



1 AND I GUESS WE CAN ALSO TAKE A SENSE OF THE COMMITTEE.  
2 SHERRY AND I HAVE TO DECIDE AS TO WHETHER IT WOULD BE  
3 USEFUL TO THE ICOC TO HAVE A SENSE OF THIS COMMITTEE GO  
4 UP TO THEM OR NOT. THERE ALSO ARE OTHER ISSUES, AND  
5 I'M A LITTLE AFRAID OF PUTTING SO MUCH TIME ON THIS, NO  
6 MATTER HOW IMPORTANT IT IS, THAT WE DON'T REALLY  
7 ADDRESS SOME OF THESE OTHER IMPORTANT ISSUES THAT HAVE  
8 TO DO WITH RECORDKEEPING AND PUBLIC ACCESSIBILITY AND  
9 THE LIKE.

10 I WOULD SUGGEST THAT WE TRY AND JUGGLE A  
11 COUPLE OF BALLS IN THE AIR, AND THAT WE DO TAKE A BREAK  
12 FOR LUNCH. IT'S ALMOST ONE. WE'RE ABOUT 45 MINUTES  
13 LATE. AND THEN COME BACK AND START WITH THE  
14 RECORDKEEPING AND ASSURANCES, TRY AND SEE IF WE CAN  
15 REACH AGREEMENT.

16 MS. LANSING: YES. SO LET'S GO TO THE OTHER  
17 ISSUES, SEE WHERE WE ARE WHEN WE COME BACK. AND IF WE  
18 DON'T HAVE TIME, WE'RE GOING TO DO THE OTHER WAY. AND  
19 THEN WE HAVE TO MAKE SURE THAT THE ICOC UNDERSTANDS  
20 THIS IS INFORMATION THEY HAVE TO VOTE ON IT, OR WE'RE  
21 IN DANGER OF NOT BEING ABLE TO CONTINUE OUR WORK.

22 CHAIRMAN LO: ANOTHER PUBLIC COMMENT.

23 MS. PASTORE: I JUST WANTED TO SUGGEST ONE  
24 THING ABOUT THAT PROCEDURE. ONE OF THE BENEFITS OF  
25 USING THE 15-DAY RENOTICE IS THAT YOU WILL GET COMMENT

1 FROM MORE PEOPLE THAN ARE IN THE ROOM TODAY. I BELIEVE  
2 IT'S REQUIRED, BUT IT CERTAINLY IS COMMON PRACTICE TO  
3 SEND THE VERSIONS TO ALL OF THE PEOPLE WHO COMMENTED,  
4 BUT ARE NOT HERE TODAY. SO YOU WILL GET A BROADER  
5 RANGE OF COMMENT THAN YOU WILL BY TRYING TO RESOLVE IT  
6 TODAY.

7 MS. LANSING: WE'VE GOT 48 HOURS. THAT'S ALL  
8 I WANT TO SAY.

9 CHAIRMAN LO: GEOFF, IS IT REALISTIC TO GET  
10 THIS NOTICED BEFORE THE DEADLINE?

11 MR. TOCHER: YES. WE'VE ALREADY IDENTIFIED  
12 OBVIOUSLY EVERYBODY WHO'S COMMENTED, AND WE ALSO  
13 MAINTAIN A RECORD OF EVERYBODY TO WHOM IT WENT OUT.  
14 WE'LL GIVE IT TO THEM AS WELL AND ALSO POST IT ON THE  
15 WEBSITE.

16 CHAIRMAN LO: ALL RIGHT. SO WITH THAT,  
17 I WILL PROPOSE WE ADJOURN FOR LUNCH. I THINK WE HAD A  
18 VERY INTERESTING AND INTENSE MORNING, AND WE ADDRESSED  
19 SOME TOUGH ISSUES. LET'S EAT AND IF WE CAN COME BACK  
20 AT 1:30, WHICH IS ABOUT 45 MINUTES FROM NOW.

21 (A RECESS WAS TAKEN.)

22 CHAIRMAN LO: WELCOME BACK. WHAT I WOULD  
23 LIKE TO DO IS TO SORT OF DIRECT OUR ATTENTION TO THIS  
24 IMPORTANT SET OF ISSUES. AS I UNDERSTAND, NO ONE IS  
25 LEFT ON THE TELEPHONE. IT'S JUST US FOLKS IN THE ROOM.

1 AND SHERRY IS GOING TO BE BACK AROUND THREE.

2 I WOULD LIKE TO GET US STARTED ON THESE  
3 ISSUES OF RECORDKEEPING AND ASSURANCES. AND IN OUR  
4 FOLDERS WE HAVE -- LET ME MAKE SURE I GOT THIS RIGHT --  
5 WE HAVE THE SUGGESTIONS FROM THE FOUNDATION FOR  
6 TAXPAYER AND CONSUMERS RIGHTS. IT'S PAGE 2. AND,  
7 GEOFF, HELP ME OUT. THERE'S A BIGGER FORM I'M TRYING  
8 TO FIND FROM THE CENTER -- AT THE END OF THAT SAME  
9 HANDOUT, THERE'S A LONGER STATEMENT FROM PRO-CHOICE  
10 ALLIANCE FOR RESPONSIBLE RESEARCH AND CENTER FOR  
11 GENETICS AND SOCIETY. AND THEY HAVE MADE A NUMBER OF  
12 SUGGESTIONS HAVING TO DO WITH RECORDKEEPING AND  
13 ASSURANCES.

14 I KNOW WE STARTED TO THINK ABOUT THIS A  
15 LITTLE AT LUNCH, BUT I'D LIKE TO KIND OF GET US STARTED  
16 ON THIS DISCUSSION BECAUSE THESE ARE, AS I SAY,  
17 IMPORTANT AND COMPLEX TOPICS. SO SOMEONE WANT TO START  
18 OUT WITH JUST OUR THOUGHTS ON THESE ISSUES AND THE  
19 SPECIFIC SUGGESTIONS?

20 DR. PETERS: MY QUESTION EARLIER WAS IN OUR  
21 MIND AS A COMMITTEE IS THIS CONNECTED OR DISCONNECTED  
22 WITH THE FREE FLOW OF SCIENTIFIC INFORMATION? ARE  
23 THERE LINES GOING TO BE DRAWN BETWEEN SCIENTIFIC  
24 RECORDKEEPING AND COMPLIANCE RECORDKEEPING, OR ARE THEY  
25 GOING TO OVERLAP? IF THEY ARE GOING TO OVERLAP, TO

1 WHAT EXTENT?

2 CHAIRMAN LO: DO YOU HAVE PRELIMINARY  
3 THOUGHTS TO ANSWER YOUR QUESTIONS?

4 DR. PETERS: I WOULD THINK THAT IN PRINCIPLE  
5 WE WOULD WANT PRIMARILY FREE FLOW OF SCIENTIFIC  
6 INFORMATION, AND COMPLIANCE WOULD BE SUBSUMED UNDER  
7 THAT. RELATED TO THAT, YOU'D WANT THE SAME RECORDS.  
8 THIS IS MY HUNCH. YOU'D WANT THE SAME RECORDS  
9 AVAILABLE FOR WHOMEVER IS INTERESTED. I'M NOT SAYING  
10 ANYTHING ABOUT AUDITS. I'M JUST SAYING ABOUT WHAT'S  
11 THE NATURE OF THE RECORDS WE'RE TALKING ABOUT?

12 DR. TAYLOR: I'D MAKE A SUGGESTION HERE, AND  
13 IT WOULD BE I REALLY LIKE THE POINTS YOU MADE EARLY ON  
14 ABOUT THIS BEING KIND OF A QUALITY ASSURANCE, QUALITY  
15 ENHANCEMENT TYPE OF A MODEL. AND THE SART, WHICH IS  
16 THE SOCIETY FOR ADVANCED REPRODUCTIVE TECHNOLOGY, OR  
17 ASSISTED REPRODUCTIVE TECHNOLOGY, AND THE CDC HAVE A  
18 PRETTY GOOD SYSTEM THAT THIS MIGHT BE ANALOGOUS TO  
19 WHERE THERE'S A REPORTING TO THE NATIONAL OFFICE OF ALL  
20 IVF STATISTICS FROM ALL IVF PROGRAMS AROUND THE  
21 COUNTRY. THE DATA ARE DEIDENTIFIED AND PLACED INTO A  
22 NATIONAL DATABASE THAT'S ACCESSIBLE TO EVERYONE WITH  
23 NUMBER OF CYCLES AND SUCCESS RATES.

24 I THINK THAT SOMETHING LIKE THAT COULD BE  
25 USED AND STILL POTENTIALLY PROTECT THE INTELLECTUAL

1 PROPERTY SO THAT WE HAVE THE DEIDENTIFICATION OF  
2 SUBJECTS THAT ARE ENROLLED, BUT WE HAVE A LIST THAT'S  
3 REPORTED, AND I WOULD SUGGEST MAYBE TO CIRM AS THE  
4 CENTRAL REPOSITORY FOR THAT INFORMATION. AND THAT  
5 COULD BE USED TO KIND OF FOLLOW COMPLIANCE, BUT PERHAPS  
6 WITHOUT HAVING ALL OF THE DETAILED INFORMATION,  
7 SCIENTIFIC DETAILED INFORMATION IN IT, AND THAT WOULD  
8 BE PUBLICLY DISCLOSED.

9 AT LEAST IT'S JUST SORT OF A MODEL THAT'S  
10 WORKED WELL IN THE IVF INDUSTRY, AND THAT ALLOWS PEOPLE  
11 TO KNOW IN THE COMMUNITY WHAT'S GOING ON IN THOSE  
12 VARIOUS PROGRAMS, BUT WITHOUT THE SPECIFIC DETAILS THAT  
13 MAYBE SOME PEOPLE CLEARLY WOULD LIKE TO HAVE ACCESS TO  
14 PERHAPS AT A SECOND LEVEL OF AUDITING OR SOMETHING.

15 CHAIRMAN LO: I GUESS I'M NOT CLEAR IN MY OWN  
16 MIND ABOUT SORT OF ALL THE DIFFERENT KINDS OF  
17 INFORMATION WE'RE TALKING ABOUT. SO YOUR SART MODEL,  
18 IT SEEMS TO ME, WOULD APPLY, FOR INSTANCE, IF YOU  
19 WANTED TO LOOK AT COMPLICATIONS OF OOCYTE RETRIEVAL.

20 DR. TAYLOR: ADVERSE EVENTS AND THINGS LIKE  
21 THAT, BUT ALSO YOU COULD HAVE SORT OF GENERIC  
22 CLASSIFICATIONS OF PROTOCOLS THAT ARE BEING  
23 INVESTIGATED AT THE DIFFERENT CIRM SITES, AN ACCOUNTING  
24 OF HOW MANY EMBRYOS OR CELL LINES OR OOCYTES WERE  
25 DONATED AT THE VARIOUS PLACES, AND HOW THEY WERE USED,

1 AND STILL HAVE -- I THINK YOU CAN PUT QUITE A BIT OF  
2 DETAIL INTO THAT AND STILL PROTECT PRESUMABLY THE  
3 INTELLECTUAL PROPERTY ISSUES THAT I SUSPECT ARE GOING  
4 TO BE SOME OF THE THORNIEST ONES TO SORT OUT.

5 CHAIRMAN LO: OTHER THOUGHTS?

6 DR. KIESSLING: COULD WE QUICKLY JUST REVIEW  
7 WHAT KINDS OF ANNUAL DOCUMENTATION IS NECESSARY NOW?  
8 THE ESCRO COMMITTEE PROVIDES, THAT'S PART OF THEIR  
9 CHARGE, RIGHT?

10 CHAIRMAN LO: LET GEOFF LOOK THIS UP EXACTLY  
11 FOR US. WE SHOULD ALSO HEAR WHAT THE STANDARDS WORKING  
12 GROUP IS LIKELY TO PROPOSE IN THEIR -- GRANTS WORKING  
13 GROUP. I DON'T KNOW IF ANY OF YOU ARE ON THAT  
14 COMMITTEE. JEFF'S ON EVERY COMMITTEE. JUST FEELS THAT  
15 WAY.

16 MR. LOMAX: IT IS ATTACHED IN THE PACKET.  
17 IT'S PART OF THE EXISTING DRAFT, AND THE MAIN SECTION  
18 IS 10120, WHICH IS ON, I BELIEVE, PAGE 18 OF THE  
19 COMPILED DOCUMENT. THEY HAVE TO DOCUMENT -- THEY HAVE  
20 TO KEEP RECORDS AND AT A MINIMUM MAINTAIN, WE'RE  
21 CALLING IT, A RESEARCH REGISTRY. AND IT'S  
22 DOCUMENTATION OF CIRM-FUNDED STEM CELL RESEARCH. THEY  
23 ARE REQUIRED TO REVIEW OR A NOTIFICATION REQUIREMENT  
24 DESCRIBED IN THE REGULATIONS, AND THOSE ARE THE -- THAT  
25 SECTION BEING REFERRED TO IS THE SECTION ON THE SCRO

1 REVIEW. AND THERE'S ALSO SOME ADDITIONAL SECTIONS  
2 THERE, WHICH I COULD READ THROUGH, ABOUT SAFETY  
3 SCREENING, CONDITION WHICH MATERIALS ARE STORED AND  
4 MAINTAINED, AND ANY ADDITIONAL REQUIREMENTS SET FORTH  
5 IN ANY OTHER REGULATION.

6 AND THE IDEA THERE IS THAT IF WE ADD  
7 ADDITIONAL THINGS, RECORDKEEPING REQUIREMENTS, THAT  
8 THEY WOULD FALL UNDER THIS SECTION. AND THEN THERE'S  
9 THE SECTION F, WHICH REALLY IS SORT OF TRACKING THE  
10 PROGRESS OF ALL GAMETES, SOMATIC CELLS, EMBRYOS, AND  
11 PRODUCTS OF SCNT. SO THOSE REQUIREMENTS ARE FOR  
12 INSTITUTIONAL RECORDKEEPING, AND THERE IS NO SPECIFIC  
13 REPORTING REQUIREMENTS OUTSIDE OF THE INSTITUTION.  
14 WE'RE JUST SAYING THESE ARE THE THINGS THAT NEED TO BE  
15 TRACKED AT THE INSTITUTIONAL LEVEL.

16 CHAIRMAN LO: ONE WAY FOR US TO THINK ABOUT  
17 THIS IS WE HAVE RECOMMENDATIONS PRESENTED TO US TO  
18 EXPAND THE RECORDKEEPING THAT THE INSTITUTION IS  
19 REQUIRED TO KEEP. WE ALSO HAVE RECOMMENDATIONS TO DO  
20 MORE THAN JUST HAVE THE INSTITUTION KEEP IT, TO  
21 DISCLOSE INFORMATION TO CIRM, TO THE LEGISLATURE, AND  
22 TO THE PUBLIC, FOR EXAMPLE. SO WE'RE SORT OF BEING  
23 ASKED TO BROADEN THE SCOPE OF THE INFORMATION COLLECTED  
24 AND BROADEN THE SCOPE OF WHO GETS THAT INFORMATION.

25 MS. CHARO: YOU KNOW, I THINK I MIGHT HAVE

1 SAID THIS BEFORE AT A PUBLIC SESSION, I'M NOT SURE, BUT  
2 WE DO EXIST IN A WORLD THAT HAS A FAIR NUMBER OF  
3 STANDARDIZED PROCEDURES FOR RECORDKEEPING AND ACCESS TO  
4 RECORDS. AND I'M LOATHE TO CREATE FROM WHOLE CLOTH NEW  
5 SYSTEMS THAT MAY OR MAY NOT BE CONSISTENT WITH OR  
6 INTERRELATE WELL WITH EXISTING SYSTEMS IN THE STATE OF  
7 CALIFORNIA AND FOR INSTITUTIONS RECEIVING NSF OR NIH  
8 GRANTS.

9 SO MY FIRST KIND OF CONCERN IS IN WRITING  
10 WHOLE NEW REPORTING REQUIREMENTS RATHER THAN WORKING ON  
11 A DRAFT THAT BEGINS WITH WHAT ARE THE REQUIREMENTS THAT  
12 THESE INSTITUTIONS ARE ALREADY SUBJECT TO; AND HOW, IF  
13 AT ALL, DO THEY NEED TO BE ADAPTED WHEN CIRM MONEY IS  
14 RECEIVED.

15 THE SECOND CONCERN I HAVE IS ABOUT WRITING  
16 RULES THAT WOULD REQUIRE RECORDKEEPING OR ACTIONS WITH  
17 RESPECT TO NON-CIRM-FUNDED ACTIVITIES. FOR EXAMPLE, IN  
18 THE PROPOSAL FROM FOUNDATION FOR TAXPAYER AND CONSUMER  
19 RIGHTS ON A REDRAFT OF SECTION 10120, IT SUGGESTS THAT  
20 THERE BE A FAIR NUMBER OF ACTIONS TAKEN BY IRB'S OR  
21 SCRO'S THAT MIGHT INVOLVE RESEARCH THAT WAS NEVER  
22 CIRM-FUNDED. I'M NOT SURE THAT WE HAVE --

23 DR. HALL: HELLO.

24 CHAIRMAN LO: WELCOME, ZACH. WE'RE STARTING  
25 TO TALK ABOUT THE PUBLIC COMMENTS WITH REGARD TO



1 RECORDKEEPING AND ASSURANCES. AND ALTA WAS JUST  
2 TALKING ABOUT HOW THERE ARE IN PLACE CURRENTLY  
3 REQUIREMENTS FOR NIH RECORDKEEPING AND REPORTING AND  
4 STATE OF CALIFORNIA RECORDKEEPING AND REPORTING. SHE  
5 WAS SUGGESTING THAT AT LEAST WE SHOULD START BY  
6 UNDERSTANDING WHAT THE CURRENT REQUIREMENTS ARE IN  
7 PLACE.

8 AND HER SECOND POINT WAS THAT HER CONCERNS  
9 ABOUT REQUIRING CIRM-FUNDED INSTITUTIONS TO REPORT ON  
10 ACTIVITIES THAT ARE NOT FUNDED BY CIRM. I'LL LET ALTA  
11 TAKE OVER.

12 MS. CHARO: NO. NO. THAT'S IT.

13 CHAIRMAN LO: DO YOU WANT TO SAY A LITTLE  
14 MORE ABOUT HOW YOU THINK WE SHOULD ADDRESS THAT?

15 MS. CHARO: WELL, FOR ONE THING, I DO  
16 CONTINUALLY FIND MYSELF THINKING THIS REALLY DOES  
17 BELONG MORE IN THE OVERALL STRUCTURE OF GRANTS  
18 ADMINISTRATION BECAUSE GRANTS ADMINISTRATION IS ABOUT  
19 WHAT IT TAKES TO GET THE MONEY AND WHAT IT TAKES TO  
20 CONTINUE GETTING THE MONEY AND WHAT IT TAKES TO CLOSE  
21 DOWN A PROJECT. IT SEEMS TO ME THE MOST NATURAL PLACE  
22 TO HANDLE THESE THINGS RATHER THAN THE ETHICAL  
23 STANDARDS FOR CONDUCT OF THE PROJECT.

24 CERTAINLY THE GRANTS ADMINISTRATION DRAFTING  
25 PROCESS MIGHT BENEFIT FROM SOME CONSULTATION FROM THE

1 CHAIR OF THIS WORKING GROUP OR ANY OTHER INTERESTED  
2 PARTY, BUT IT FEELS LIKE THIS --

3 DR. HALL: HELLO.

4 DR. PRIETO: I THINK MAYBE HE CAN'T HEAR YOU.  
5 CAN YOU HEAR US, ZACH?

6 DR. HALL: YES. WE'VE GOT IT NOW. THANK YOU  
7 VERY MUCH.

8 MS. CHARO: BUT IT FEELS LIKE THESE RULES GO  
9 BEYOND WHAT AN ETHICS STANDARDS GROUP WOULD DO. I DO  
10 APPRECIATE THE SUGGESTION THAT YOUR ETHICS STANDARDS  
11 DON'T MEAN MUCH IF THEY ARE NOT ENFORCEABLE. SO THE  
12 POINT IS TAKEN. IT'S JUST THAT TECHNIQUES FOR  
13 ENFORCEMENT, I THINK, HAVE TO BE INTEGRATED INTO GRANTS  
14 ADMINISTRATION GENERALLY. BEGIN WITH THE KINDS OF  
15 REQUIREMENTS THAT PEOPLE ARE ALREADY UNDER OR MODELED  
16 AFTER THE KINDS OF REQUIREMENTS THAT PEOPLE WOULD BE  
17 UNDER UNDER OTHER KINDS OF GRANTING MECHANISMS IN  
18 CALIFORNIA FOR THINGS LIKE BREAST CANCER AND AIDS  
19 RESEARCH AND OTHERS.

20 DR. PRIETO: ALTA, ARE YOU SUGGESTING THAT WE  
21 THEN JUST REFER THIS WHOLE TOPIC TO THE GRANTS  
22 ADMINISTRATION POLICY?

23 MS. CHARO: I WOULD SUGGEST THAT WE SHOULD  
24 SIMPLY ASK WHETHER THERE'S ANY PORTION OF THIS THAT WE  
25 THINK IS APPROPRIATELY ISOLATED IN THE ETHICS

1 STANDARDS. IF THERE IS, WE ADDRESS THAT AND LEAVE THE  
2 REMAINDER TO MORE A COMPREHENSIVE SET OF GRANTS  
3 ADMINISTRATION RULES, WHICH WILL TACKLE THIS AND OTHER  
4 THINGS HAVING TO DO WITH RECORDKEEPING, AUDITS,  
5 ASSURANCES, OVERSIGHT, ETC.

6 DR. HALL: THIS IS ZACH. OUR CONNECTION WENT  
7 OUT FOR A WHILE. YOU'RE NOW PRESUMABLY TALKING ABOUT  
8 THE ACCOUNTABILITY PORTIONS OR ADDRESSING SOME OF THE  
9 ISSUES THAT JOHN SIMPSON TALKED ABOUT?

10 CHAIRMAN LO: YES, EXACTLY.

11 DR. HALL: YES. SOME OF THESE CERTAINLY WILL  
12 BE ADDRESSED THERE. I'M ACTUALLY NOT -- I CAME IN  
13 RATHER LATE, AND I'M NOT QUITE SURE WHAT'S BEING  
14 PROPOSED IN SOME CASES. FOR EXAMPLE, FOR THE  
15 ASSURANCES, I DON'T KNOW IF JOHN OR OTHERS IMAGINE THAT  
16 THERE'S AN ASSURANCE FOR EACH GRANT, BUT IN GENERAL  
17 WHAT WE WILL DO IS WE WILL HAVE, ALL OF OUR GRANTS  
18 ADMINISTRATION POLICIES, WE WILL ASK EACH INSTITUTION  
19 TO SIGN A STATEMENT SAYING THAT THEY WILL ABIDE BY  
20 THOSE POLICIES. THAT IS WHAT WILL BE THE ASSURANCE.  
21 THEY WILL NOT BE ABLE TO GET MONEY FROM US UNLESS THEY  
22 DO THAT.

23 AND JUST AS ALREADY, THE TRAINING GRANTS  
24 REQUIRE SIGNATURE BY EACH OF THE INSTITUTIONS THAT THEY  
25 ABIDE WITH OUR -- AGREED WITH AND WILL ABIDE BY OUR

1 GRANTS ADMINISTRATION POLICY FOR TRAINING GRANTS.

2 SO WHAT GOES ON IN THIS COMMITTEE, WHAT GOES  
3 ON IN THE INTELLECTUAL POLICY COMMITTEE WILL -- THE  
4 INTELLECTUAL PROPERTY POLICY COMMITTEE FOR NON-PROFIT  
5 INSTITUTIONS WILL THEN ALL BE SUBSUMED UNDER OUR GRANTS  
6 ADMINISTRATION POLICY, AND WE WILL DEAL WITH THAT  
7 THERE.

8 SOME OF THE ISSUES THAT ARE RAISED HERE WOULD  
9 BE QUITE CUMBERSOME FOR US TO CARRY OUT. AND I THINK  
10 THE REAL POINT IS THAT THE WAY THE SYSTEM WORKS IS WE  
11 HOLD THE INSTITUTION ACCOUNTABLE. WE ARE ABLE TO COME  
12 IN AND LOOK AT THEIR RECORDS OR TO AUDIT AT ANY TIME.  
13 THEY ARE RESPONSIBLE TO US, BUT THE ONGOING DAY-BY-DAY  
14 ENFORCEABILITY IS NOT SOMETHING THAT WE -- IT'S NOT UP  
15 TO US TO SUPERVISE THEIR ESCRO'S. IT'S UP TO THEM TO  
16 DO IT AND UP TO US TO THEN CHECK ON THAT. THEY WILL,  
17 OF COURSE, BY THE TERMS OF THE GRANTS ADMINISTRATION  
18 POLICY, THEY WILL FILE SUMMARIES OF THE GRANTS THAT  
19 THEY -- RESEARCH CARRIED OUT UNDER THE GRANTS THAT WE  
20 GIVE THEM. THEY WILL, OF COURSE, FILE ANY ADVERSE  
21 EVENTS. ALL OF THAT WILL BE SPECIFIED IN PROBABLY AN  
22 RFA WE WOULD DO, AND ALL THIS WILL BE TAKEN CARE OF.

23 SO IT'S A LITTLE BIT OVERKILL IN THIS  
24 CONTEXT. I UNDERSTAND THE CONCERNS, AND WE CERTAINLY  
25 WANT TO HAVE WORK CARRIED OUT ACCORDING TO THE HIGHEST

1 MEDICAL AND ETHICAL STANDARDS, BUT WE WILL NEED TO WORK  
2 ON THAT IN A LARGER CONTEXT RATHER THAN THE ONE HERE.

3 MR. LOMAX: ZACH, THIS IS GEOFF. I JUST  
4 WANTED TO ALSO, FOR THE BENEFIT OF THE COMMITTEE,  
5 REMIND THEM THAT IN THE GRANTS ADMINISTRATION POLICY  
6 ITSELF, PART OF COMPLYING WITH THE GRANTS  
7 ADMINISTRATION POLICY IS COMPLYING WITH THE MEDICAL AND  
8 ETHICAL STANDARDS, WHICH ARE CITED.

9 DR. HALL: ABSOLUTELY. THIS WILL BECOME PART  
10 OF, AS WILL THE INTELLECTUAL PROPERTY POLICY, ALL WILL  
11 BECOME PART OF THE POLICY THAT THEY'RE EXPECTED TO SIGN  
12 OFF ON THAT THEY AGREE TO, AS I SAY, THAT THEY WILL  
13 ABIDE BY THE PROVISIONS IN THOSE POLICIES. AND THAT IS  
14 WHY WE'VE HAD DISCUSSIONS WITH THEM ON VARIOUS ISSUES  
15 AS WE GO FORWARD. AND YOU WILL NOTICE THAT SOME OF THE  
16 COMMENTS FOR THIS COME IN FROM PEOPLE WHO'VE HAD  
17 EXPERIENCE WITH IRB'S, FOR EXAMPLE, IN THEIR  
18 INSTITUTIONS, AND THEY KNOW AND UNDERSTAND THAT WHAT  
19 THIS GOES THROUGH, THEY WILL HAVE TO ABIDE BY THOSE  
20 PROVISIONS. AND WE CERTAINLY WILL WORK OUT THE MEANS  
21 FOR CHECKING ON THAT AND WILL DO THAT IN THE CONTEXT OF  
22 THE GRANTS ADMINISTRATION POLICY.

23 CHAIRMAN LO: ZACH, COULD YOU ALSO CLARIFY  
24 THE GRANTS ADMINISTRATION POLICY IS BEING ACTIVELY  
25 DEVELOPED AND IS FORTHCOMING; IS THAT CORRECT?

1 DR. HALL: YES. THE BOARD HEARD A DRAFT OF  
2 THAT AT OUR LAST MEETING. WE'RE CONTINUING TO WORK ON  
3 IT. WE WILL COME BACK. IN FACT, I THINK THEY HAVE  
4 BEEN INFORMED ABOUT IT ONCE. THEY CONSIDERED IT LAST  
5 TIME. THERE WERE SOME UNRESOLVED ISSUES. IT WILL COME  
6 UP AGAIN IN OUR JUNE MEETING. AND THEN JUST AS IN THE  
7 CASE OF THE MEDICAL AND ETHICAL STANDARDS, ALL OF THAT  
8 THEN, IF FINALLY APPROVED BY THE ICOC, WILL THEN BE  
9 SUBMITTED TO THE OFFICE OF ADMINISTRATIVE LAW AND WILL  
10 GO THROUGH A PUBLIC HEARING PROCESS, JUST AS IS BEING  
11 DONE HERE.

12 CHAIRMAN LO: ZACH, IF I CAN CONTINUE WITH A  
13 COUPLE MORE QUESTIONS.

14 DR. HALL: PLEASE.

15 CHAIRMAN LO: HOW CAN THE STANDARDS WORKING  
16 GROUP BE USEFUL BOTH TO CIRM AND TO THE GRANTS WORKING  
17 GROUP? IT SOUNDS AS IF THE GRANTS WORKING GROUP IS  
18 GOING TO HAVE RESPONSIBILITY FOR MORE DETAILED  
19 REQUIREMENTS TO SORT OF BE AWARDED A GRANT AND TO  
20 CONTINUE TO RECEIVE FUNDING. ARE THERE THINGS, ISSUES  
21 THAT -- ARE THERE THINGS THAT WE CAN HELP WITH IN TERMS  
22 OF DISCUSSING ISSUES, OR IS THIS SOMETHING BEST LEFT  
23 PROCEDURALLY TO THE GRANTS WORKING GROUP?

24 DR. HALL: NO. I THINK THIS WILL -- FOR  
25 EXAMPLE, ONE OF THE ISSUES THAT WE DISCUSSED HERE, I

1 THINK THERE WILL BE A BACK AND FORTH, BUT ONE OF THE  
2 ISSUES THAT WE DISCUSSED HERE WAS THAT IN TERMS OF  
3 INFORMED CONSENT FORMS, AND I THINK WE DISCUSSED THIS  
4 SPECIFICALLY IN TERMS OF COMPENSATION, IF I'M NOT  
5 MISTAKEN, WE LET THE INSTITUTIONS DEAL WITH THAT WITHIN  
6 CERTAIN BROAD GUIDELINES WITH THE IDEA THAT WHEN WE  
7 ISSUE AN RFA, WE WILL ASK THAT EACH, FOR WHICH THIS IS  
8 RELEVANT, THAT EACH GRANT THAT PROPOSES TO USE EGG  
9 DONATION, TO SUBMIT AS PART OF THAT GRANT HOW THEY  
10 PROPOSE TO CARRY OUT THEIR REIMBURSEMENT.

11 I'M SORRY. I MISSPOKE BEFORE, COMPENSATION,  
12 BUT REIMBURSEMENT OF EXPENSES, ACCORDING TO YOUR  
13 GUIDELINES. AND THEN THOSE WILL BE FLAGGED. AND IF WE  
14 RUN INTO TROUBLE WITH ISSUES EITHER WITH REGARD TO A  
15 SPECIFIC INSTITUTION OR WITH REGARD TO OUR GENERAL  
16 POLICY, WE WILL COME BACK TO YOU TO HELP US SORT  
17 THROUGH THE MEDICAL AND ETHICAL STANDARDS. I THINK  
18 IT'S NOT USEFUL FOR YOUR TIME TO REVIEW EACH OF OUR  
19 GRANTS. AND, IN FACT, THE WHOLE POINT IS THAT THE  
20 ESCRO'S WILL CARRY OUT PRELIMINARY REVIEW OF THAT. AND  
21 THE REAL PURPOSE, THOUGH, IS FOR THOSE ISSUES OF  
22 SPECIAL SENSITIVITY, TO HIGHLIGHT THOSE AND REQUIRE IN  
23 THE RFA THAT SPECIFICATION BE GIVEN, AND WE CAN SEE  
24 EXACTLY HOW IT'S BEING DONE IN PRACTICE.

25 CHAIRMAN LO: SO IT SOUNDS LIKE NOT NOW, BUT

1 IN THE FUTURE, AS RFA'S ARE BEING DEVELOPED, THIS  
2 WORKING GROUP WILL HAVE INPUT AS TO WHETHER THERE'S  
3 SPECIFIC ISSUES OF SUCH A HEIGHTENED ETHICAL CONCERN  
4 THAT WE WOULD WANT ADDITIONAL -- WE WANT SPECIFIC  
5 INFORMATION FROM THE APPLICANTS OR AWARDEES.

6 DR. HALL: AS SHERRY HAS SAID A NUMBER OF  
7 TIMES, DEVELOPING ALL THIS IS VERY MUCH A WORK IN  
8 PROGRESS. AND FOR SOME OF THESE, EXACTLY HOW WE'RE  
9 GOING TO DO IT AND HOW IT WILL WORK ARE ISSUES THAT  
10 REMAIN TO BE DECIDED. WHAT WE WANT FROM YOU ARE THE  
11 BROAD GUIDELINES. AND PART OF THE POINT IS THAT, AS WE  
12 DISCUSSED BEFORE, IF THINGS ARE TOO SPECIFIC, THEN THEY  
13 WOULD HAVE STATE REGULATIONS, AND IT BECOMES A VERY  
14 LARGE JOB TO CHANGE THEM. IT CAN BE DONE. THERE'S NO  
15 QUESTION ABOUT IT, BUT IT'S A JOB AND IT TAKES TIME.  
16 AND SO WE WANT WITHIN THE BROAD GUIDELINES THE  
17 FLEXIBILITY TO BE ABLE TO WORK OUT THE BEST WAY TO  
18 HANDLE THESE SITUATIONS, NO. 1, WITHOUT BURDENING THE  
19 INSTITUTIONS AND THE INVESTIGATORS WITH AN IMPOSSIBLE  
20 AMOUNT OF PAPERWORK; AND, NO. 2, WE WANT A REALLY  
21 EFFECTIVE SYSTEM. AND WE WILL NEED TO SORT OUT HOW  
22 WE'RE GOING TO DO THAT.

23 SO I THINK WE NEED THE BROAD STATEMENTS AND  
24 THE BROAD REGULATIONS SO THAT THEY WILL BE HELD  
25 ACCOUNTABLE AND MUST GIVE US ASSURANCE THAT THESE ARE



1 BEING FOLLOWED OUT. BUT I THINK DOING THINGS LIKE  
2 ASKING -- IT'S NOT QUITE CLEAR -- ASKING FOR ASSURANCE  
3 EACH YEAR IS NOT CLEAR TO ME WHAT THAT GAINS. IT'S IN  
4 THE FORM OF A CONTRACT IN A SENSE. WE CONTRACT WITH A  
5 PARTICULAR RESEARCH INSTITUTION THAT THEY WILL ABIDE BY  
6 THE RULES, THEY WILL DO ALL THE THINGS THAT WE ASK THEM  
7 TO DO, AND THEN WE GIVE THEM THE MONEY.

8 SO THEN IT'S UP TO US TO HOLD THEM  
9 ACCOUNTABLE FOR THAT, BUT THAT DOESN'T MEAN, I THINK,  
10 THAT WE -- WE CAN'T DO THAT WITH TOO FINE A GRAIN. IT  
11 IS THE INSTITUTION'S RESPONSIBILITY. THEY HAVE A  
12 HISTORY OF DOING IT WITH THE IRB. AND AS WE ALL KNOW,  
13 THEY HAVE CONSIDERABLE PERSONNEL AND RESOURCES  
14 DEDICATED TO BEING IN COMPLIANCE ALREADY WITH THE  
15 FEDERAL REGULATIONS. AND SO THEY WILL SIMPLY ADD TO  
16 THAT HOW TO DO THIS FOR THE STATE. AND WE WILL NEED TO  
17 WORK OUT THE BEST WAY TO MONITOR THAT AND ASSURE  
18 OURSELVES AND THE PUBLIC THAT WE ARE, INDEED, GETTING  
19 COMPLIANCE.

20 DR. TAYLOR: I THINK THESE ISSUES REALLY DEAL  
21 NICELY WITH THE WHOLE COMPLIANCE COMPONENT, BUT MAYBE  
22 NOT VERY MUCH WITH THE PUBLIC ASSURANCE COMPONENT. SO  
23 I'M WONDERING WHAT TYPE OF REPORTING PROCESS AND PUBLIC  
24 DISCLOSURE MIGHT BE THE BEST TYPE OF POLICY TO, AND  
25 MAYBE THIS ISN'T THE LEVEL TO DO IT, BUT ANNUAL

1       REPORTS, DATABASE REGISTRY, THINGS THAT WOULD KIND OF  
2       BE PUBLICLY AVAILABLE SO THAT WHILE WE'RE NOT IN THE  
3       NITTY-GRITTY OF COMPLIANCE, SO THAT THE TAXPAYERS OF  
4       CALIFORNIA WOULD SEE AT LEAST A LITTLE BIT OF WHAT'S  
5       HAPPENING WITH THEIR MONEY AND THE DIRECTIONS THAT THE  
6       PROJECTS ARE LEADING.

7                 DR. HALL: I IMAGINE THAT THE WAY IT WILL  
8       WORK, WE CERTAINLY WILL REQUIRE THAT EACH INSTITUTION  
9       SUBMIT A YEARLY REPORT TO US. SO, IN EFFECT, IF THERE  
10      ARE ANY ADVERSE EVENTS THAT OCCUR OR IF THERE'S SOME  
11      FAILURE OF AN INDIVIDUAL LABORATORY, WE WILL TELL THEM  
12      WE NEED IMMEDIATE NOTIFICATION. AND THEN WE NEED TO  
13      KNOW -- WE WILL ASK FOR WRITTEN ASSURANCE OF WHAT STEPS  
14      HAVE BEEN TAKEN TO CORRECT THIS AFTER THE FACT. AND WE  
15      WILL MAKE JUDGMENTS ABOUT WHETHER THOSE STEPS ARE  
16      ADEQUATE OR NOT. AND THEN I THINK AS AN INSTITUTE, WE  
17      WILL NEED TO MAKE, AS PART OF OUR ANNUAL REPORT, AND  
18      THERE IS IN PROPOSITION 71 PROVISIONS FOR DOING THAT.

19                WE'RE IN THE PROCESS NOW ACTUALLY OF PUTTING  
20      TOGETHER ONE FOR THE LAST YEAR, ALTHOUGH WE DIDN'T HAVE  
21      ANY GRANTS, SO THAT PART OF IS NOT THERE, BUT WE WOULD  
22      CERTAINLY LIST ALL THE GRANTS THAT WE AWARD. WE WOULD  
23      ALSO GIVE INFORMATION, OVERALL INFORMATION, ABOUT THE  
24      NUMBER OF GRANTS AWARDED AND THE NUMBER OF  
25      APPLICATIONS, INFORMATION ABOUT OVERALL DISEASE AREAS

1 WHERE THAT'S POSSIBLE, DISTRIBUTION, ALL THAT  
2 INFORMATION WOULD BE AVAILABLE. CERTAINLY PART OF THAT  
3 WOULD BE ANY FAILURES OF COMPLIANCE, ANY ADVERSE EVENTS  
4 THAT HAVE HAPPENED, AND THIS WOULD BE PART OF OUR  
5 PUBLIC RECORD AND PART OF OUR ANNUAL REPORT, WHICH  
6 WOULD BE A PUBLIC DOCUMENT. SO ALL OF THAT WILL BE  
7 THERE FOR THE PUBLIC TO SEE.

8 CHAIRMAN LO: OKAY. KEN OLDEN HAD SOME  
9 COMMENTS.

10 DR. OLDEN: ON THE SUGGESTIONS THAT WERE  
11 MADE, I GUESS THEY WERE MADE BECAUSE WE DIDN'T MENTION  
12 THEM IN OUR SUGGESTIONS. IT SEEMS TO ME THAT FOUR OF  
13 THEM, I BET NO ONE WOULD HAVE ANY PROBLEMS WITH. SO IT  
14 SEEMS TO ME THAT, FOR EXAMPLE, AS ZACH JUST SAID,  
15 REPORTING OF ADVERSE EVENTS. AND NIH ALREADY REQUIRES  
16 THAT. WHY DON'T WE SAY IN OUR REGS THAT WE ALSO  
17 REQUIRE THAT REPORTING BE MADE IN THIS CASE AS WELL.  
18 IT'S JUST A MATTER OF SAYING IT. I DON'T THINK THERE'S  
19 ANYBODY WHO OPPOSES THAT. I THINK WE INTEND TO DO THAT  
20 ANYWAY, AS ZACH INDICATED.

21 THERE'S THREE OTHERS THAT I THINK ARE JUST AS  
22 EASY. FOR EXAMPLE, THE FIRST ONE IS THAT THERE'S A  
23 SUMMARY PUBLISHED AND MADE AVAILABLE OF, AND I WOULD  
24 SAY OF THE FUNDED, AND SURELY WE INTEND TO DO THAT  
25 ANYWAY, POST ON OUR HOME PAGE AN ABSTRACT OF ALL THE

1 GRANTS THAT ARE FUNDED. AND THE PUBLIC SHOULD HAVE  
2 ACCESS TO THAT, AND I THINK WE COULD DO THAT.

3 THEN THEY TALK ABOUT THE DEMOGRAPHICS, AND I  
4 THINK THAT'S IMPORTANT AS WELL, OF PROVIDERS OF THE  
5 OOCYTES. THAT'S IMPORTANT INFORMATION, IT SEEMS TO ME,  
6 FOR PEOPLE.

7 AND FINALLY, THE HEALTH OUTCOMES OF OOCYTE  
8 DONORS IS GOOD INFORMATION TO HAVE. AND IT SHOULD BE  
9 COLLATED ON A STATEWIDE BASIS FOR THE WHOLE INVESTMENT.  
10 SO I THINK THOSE THREE THINGS ARE VERY EASY TO DO, AND  
11 WE SHOULD ACCEPT THEM AND INCORPORATE THEM INTO OUR  
12 SUGGESTIONS.

13 DR. HALL: I THINK WE NEED TO BE A LITTLE  
14 MORE THOUGHTFUL ABOUT IT. THESE HAVE COME IN AT THE  
15 LAST MOMENT. I CERTAINLY AGREE WITH YOU THAT SOME OF  
16 THIS PROPOSED RESEARCH ACTIVITY, WE NOW HAVE SUMMARIES  
17 ACTUALLY OF ALL OF THE APPLICATIONS. THEY'RE PUBLIC  
18 INFORMATION AT OUR ICOC MEETING. CERTAINLY THE GRANTS  
19 THAT ARE FUNDED, THE SCHOOLS, THE NAME OF THE  
20 INVESTIGATORS, A DESCRIPTION OF THE PROPOSED RESEARCH  
21 ACTIVITIES, WE ALSO HAVE PROGRESS REPORTS FROM ALL  
22 THOSE GRANTS WE FUND. I MEAN THERE'S QUITE A BIT OF  
23 INFORMATION THAT WE WILL COLLECT.

24 THE DEMOGRAPHICS OF THE PROVIDERS OF OOCYTES  
25 OR EMBRYOS USED IN THE DERIVATION OF THESE CELL LINES

1 IS RATHER VAGUE. I THINK THAT -- WITHOUT MORE  
2 INFORMATION, I THINK THAT IS NOT A USEFUL THING TO  
3 REQUIRE. WE HAVE TO SAY WHAT IT IS WE WANT, WE HAVE TO  
4 THINK IT THROUGH, WE HAVE TO THINK IN TERMS OF PRIVACY  
5 ISSUES. I THINK THAT HAS TO BE RATHER CAREFULLY  
6 CRAFTED BEFORE WE DO ANYTHING LIKE THAT.

7 I THINK A SUMMARY OF RESULTS OF ANY  
8 CIRM-FUNDED RESEARCH OR CLINICAL TRIALS IS CERTAINLY  
9 PART OF OUR PROGRESS REPORTS. WE WOULD EXPECT THAT.  
10 ANY SIGNIFICANT ADVERSE REACTIONS IN A CLINICAL TRIAL,  
11 I THINK THAT IS ALMOST TRIVIAL. WE, OF COURSE -- I  
12 DON'T MEAN IT IS TRIVIAL, BUT IT IS -- I COULDN'T  
13 IMAGINE NOT ASKING FOR THAT, AND WE WILL HAVE THAT IN  
14 OUR GRANTS ADMINISTRATION POLICY. SO I THINK A LOT OF  
15 THESE THINGS WILL BE WORKED IN. SOME OF THEM WILL NOT  
16 BE. I THINK THE DISCLOSURE OF THE PERSONAL,  
17 PROFESSIONAL, AND FINANCIAL INTEREST IN BIOTECHNOLOGY  
18 OR BIOMEDICAL COMPANIES OF SCRO MEMBERS, I THINK THAT  
19 IS NOT VERY USEFUL ACTUALLY.

20 DR. OLDEN: I AGREE.

21 DR. HALL: AND I THINK -- SO I THINK THESE  
22 ARE ISSUES. THEY CAME IN LATE. WE WILL WORK THEM  
23 OVER, AND I THINK THERE ARE A LOT OF GOOD IDEAS IN  
24 HERE, BUT I THINK THEY ARE NOT READY FOR REGULATORY  
25 LANGUAGE, AT LEAST IN THEIR CURRENT FORM. AND ALSO, WE

1 WILL NEED TO MAKE SURE HOW THEY FIT IN TO THE VARIOUS  
2 OVERALL, INTERLOCKING POLICIES THAT WE PUT TOGETHER.  
3 SO I THINK THE BEST, IN TERMS OF THE ACTION OF THE  
4 COMMITTEE, I THINK THE BEST THING THAT ONE COULD DO,  
5 THE WORKING GROUP, IS TO RECOMMEND THAT WE CAREFULLY  
6 LOOK AT THESE, THAT WE TAKE INTO ACCOUNT THE OVERALL  
7 AIMS OF THOSE WHO PROPOSE THEM, AND THAT WE THEN  
8 ADDRESS THEM IN THE VARIOUS POLICIES.

9 I THINK WE CAN CERTAINLY, AS PART OF THE  
10 PUBLIC PROCESS, WE WILL BE REQUIRED TO SAY IN WRITING  
11 EVENTUALLY HOW EACH OF THESE WILL BE HANDLED, AS I  
12 UNDERSTAND, OR OUR REASONS FOR NOT INCORPORATING THEM.  
13 SO I THINK THAT WILL DEFINITELY ADDRESS EACH OF THESE  
14 IN ESSENTIALLY A FORMAL WAY. BUT I DON'T THINK -- FOR  
15 THE MOMENT, I DON'T THINK IT'S APPROPRIATE ON SHORT  
16 PREPARATION AND SHORT TIME SPAN TO SORT OF PUT THESE  
17 INTO THE PROCESS THAT WE HAVE. WE NEED TO PUT MORE  
18 THOUGHT AND CARE INTO IT. ANYHOW, WE APPRECIATE THE  
19 SUGGESTIONS.

20 CHAIRMAN LO: SO, ZACH, LET ME MAKE SURE I  
21 UNDERSTAND CORRECTLY. IT SOUNDS LIKE THESE ISSUES WILL  
22 BE TAKEN UP BY THE GRANTS WORKING GROUP AND CONSIDERED  
23 WITH GREAT THOROUGHNESS. AND WHAT WE PROBABLY SHOULD  
24 DO IS NOT SO MUCH PAY ATTENTION TO SPECIFIC ISSUES. I  
25 THINK IT WAS HELPFUL FOR KEN AND ALTA AND ROB TAYLOR TO

1 MAKE THEIR COMMENTS, BUT RATHER THAN OUR SORT OF  
2 DUPLICATING THE WORK OF THE GRANTS WORKING GROUP, WE  
3 SHOULD SORT OF JUST RECOMMEND THAT THE GRANTS WORKING  
4 GROUP AND THE ICOC CONSIDER THESE THOUGHTFUL COMMENTS.  
5 AND WE SUPPORT, I THINK, THE NOTION OF ACCOUNTABILITY  
6 AND APPROPRIATE TRANSPARENCY AND TO BE AVAILABLE FOR  
7 CONSULTATION IF THERE ARE SORT OF ISSUES THAT THE  
8 GRANTS WORKING GROUP FEELS SORT OF TAKE AN ETHICAL  
9 TWIST. GEOFF CERTAINLY HAS ALWAYS SERVED AS A VERY  
10 USEFUL BRIDGE BETWEEN THE TWO COMMITTEES.

11 DR. HALL: I THINK IT GOES WITHOUT SAYING.  
12 THIS WORKING GROUP IS PUTTING IN AN ENORMOUS AMOUNT OF  
13 WORK TO COME UP WITH THESE STANDARDS. AND WE WANT THEM  
14 FOLLOWED. THERE IS NO QUESTION ABOUT THAT, BUT WE HAVE  
15 TO CRAFT EXACTLY HOW WE'RE GOING TO DO THAT. AND I  
16 THINK THE JOB OF THE COMMITTEE IS TO SET THE STANDARDS,  
17 AND I THINK WE WILL WORRY ABOUT THE MECHANISMS FOR  
18 COMPLIANCE WITHIN THE GRANTS ADMINISTRATION POLICY.  
19 AND WE CERTAINLY WILL ADDRESS THESE ISSUES.

20 CHAIRMAN LO: OKAY. OTHER COMMENTS BY  
21 COMMITTEE MEMBERS?

22 DR. OLDEN: JUST ONE THING, BERNIE. WE DID  
23 HAVE A SPECIAL CONCERN, I BELIEVE, AT THE VERY FIRST  
24 MEETING ABOUT DEMOGRAPHICS. AND SO WE ACTUALLY  
25 INSERTED LANGUAGE TO ADDRESS THAT. SO I WOULD JUST

1 URGE AND ENCOURAGE ZACH AND HIS GROUP NOT TO -- I'M  
2 SURE THEY'LL GIVE CONSIDERABLE THOUGHT TO THAT.

3 CHAIRMAN LO: I THINK KEN'S RIGHT, THAT THIS  
4 WAS THE SENSE OF OUR GROUP AT A VERY EARLY MEETING, AND  
5 WE PUT IT IN THE PRELIMINARY REGULATIONS AND THEN TOOK  
6 IT OUT BECAUSE WE DIDN'T QUITE HAVE IT RIGHT.

7 DR. HALL: LET ME JUST ASSURE KEN THAT, KEN,  
8 WE'RE IN THE PROCESS OF PUTTING TOGETHER A STRATEGIC  
9 PLAN, A STRATEGIC PLAN FOR OUR WORK. AND ONE OF THE  
10 ISSUES THERE IS HOW TO ASSURE DIVERSITY IN THE CELL  
11 LINES THAT WE DERIVE. AND WE, IN FACT, PLAN ON HAVING  
12 A SPECIAL FOCUS GROUP ON THAT ISSUE. SO I THINK NOT  
13 SIMPLY IN THE NEGATIVE WAY, BUT IN A POSITIVE WAY, THAT  
14 EACH VICINITY REPORT TO US WHETHER YOU'VE DONE THIS OR  
15 NOT. I THINK WE ARE GOING TO TAKE POSITIVE STEPS TO  
16 MAKE SURE THAT WE ARE ABLE TO GET THE KIND OF DIVERSITY  
17 I THINK ALL OF US BELIEVE WE NEED GOING FORWARD IF THIS  
18 IS TO BE SUCCESSFUL AS A THERAPY.

19 DR. OLDEN: THANKS, ZACH.

20 CHAIRMAN LO: ZACH, JUST A POINT OF  
21 INFORMATION. BEFORE YOU JOINED THE CALL, ROB TAYLOR  
22 POINTED OUT THAT SART, TOGETHER WITH THE CDC, HAS  
23 DEVELOPED A SORT OF MODEL OF REPORTING OUTCOMES IN  
24 INFERTILITY TREATMENT AND ADVERSE EVENTS, AND THEY  
25 PROVIDED AGGREGATE ANONYMIZED DATA TO PROTECT



1 CONFIDENTIALITY TO GIVE SORT OF AN OVERVIEW OF  
2 OUTCOMES. I GUESS, AGAIN, WE JUST SORT OF POINT THAT  
3 OUT AS A MODEL THAT THE GRANTS WORKING GROUP CAN USE IN  
4 THEIR DELIBERATIONS.

5 DR. HALL: I'M DELIGHTED TO HEAR THAT. AND  
6 WE WILL CERTAINLY LOOK AT THAT MODEL AND MAKE USE OF IT  
7 AS MUCH AS WE CAN. I THINK THE ISSUE OF EXACTLY HOW  
8 THE REPORTING WILL BE STRUCTURED IS SOMETHING WE NEED  
9 TO PAY ATTENTION TO. AND, AGAIN, I THINK WE HAVE TO BE  
10 CAREFUL ABOUT FREEZING THIS INTO STATE REGULATIONS. WE  
11 WANT TO HAVE FLEXIBILITY TO BE ABLE TO CHANGE IF WE SEE  
12 A BETTER WAY OF DOING IT OR A BETTER SYSTEM OF DOING  
13 IT. AND THE OTHER THING THAT WE ALSO DO NEED TO WORK  
14 OUT IS HOW TO ASSURE COMPLIANCE. I THINK ANN  
15 KIESSLING, I MAY BE MISQUOTING YOU, ANN, BUT I THINK  
16 YOU SAID AT ONE POINT THAT THE ONLY WAY TO ASSURE THAT,  
17 REALLY ASSURE THAT THE INFORMED CONSENT IS GIVEN IS TO  
18 HAVE A CIRM MEMBER PRESENT EACH TIME THERE IS INFORMED  
19 CONSENT GIVEN. WE CAN'T DO THAT OBVIOUSLY. SO WE ARE  
20 GOING TO HAVE TO HAVE MECHANISMS OF INSPECTION  
21 ESSENTIALLY THAT LET US MONITOR WHAT GOES ON IN A WAY  
22 THAT IS COOPERATIVE, BUT INDEPENDENT OF OUR  
23 INSTITUTIONS.

24 DR. KIESSLING: THAT WASN'T MY IDEA, ZACH.

25 DR. HALL: I KNEW IT WASN'T YOUR IDEA. I

1 THINK YOUR POINT WAS THAT IT WAS VERY DIFFICULT TO DO  
2 UNLESS SOMEBODY WAS RIGHT ON SITE. I DIDN'T MEAN TO  
3 IMPLICATE YOU IN THIS, ANN. BUT ANYHOW, IT IS THE  
4 POINT THAT IT IS A CHALLENGE TO BE SURE THAT THE  
5 PROCEDURES ARE FOLLOWED AND THAT WE WILL WANT TO KEEP  
6 AN EYE ON THAT. I THINK WE MAY HAVE A CHANCE EVEN TO  
7 BE CREATIVE ABOUT AND MAYBE WE CAN HAVE SOME STUDIES  
8 OF. I THINK THIS WOULD BE VERY IMPORTANT. ONE OF THE  
9 THINGS THAT WE WILL ADDRESS AS WE GO FORWARD, BOTH HERE  
10 AND WITH OUR EGG DONATION MEETING, IN THE SENSE OF  
11 MEDICAL RISK IS WHAT KIND OF STUDIES MIGHT WE FUND OR  
12 PUT TOGETHER, WHAT KIND OF INFORMATION SHOULD WE BE  
13 COLLECTING, NOT JUST TO PROVIDE THE PUBLIC RECORD, BUT  
14 ACTUALLY INFORMATION THAT WOULD HELP US THINK ABOUT HOW  
15 WE CAN DO OUR JOB BETTER. I THINK THAT WILL BE AN  
16 IMPORTANT CONSIDERATION FOR US. AND SO I WANT TO SEE  
17 US NOT SIMPLY ACT IN A SORT OF POLICING ROLE, BUT MUCH  
18 MORE AN ACTIVE ROLE, SAYING WE WANT THESE THINGS TO BE  
19 DONE WELL, AND WE'RE WILLING TO SPEND SOME MONEY TO  
20 CARRY OUT CAREFUL AND GOOD STUDIES THAT MIGHT IMPROVE  
21 THESE PRACTICES.

22 CHAIRMAN LO: OTHER COMMENTS WITH REGARD TO  
23 THIS?

24 MR. SHEEHY: JUST ONE. THIS IS TO ECHO  
25 ALTA'S POINT. I THINK WE DECIDED EARLY ON THAT WE

1 WEREN'T GOING TO BE THE SUPER REGULATORS FOR STEM CELL  
2 RESEARCH IN CALIFORNIA. SO I THINK WE SHOULD BE CLEAR  
3 THAT STEM CELL RESEARCH THAT IS NOT FUNDED BY CIRM IS  
4 NOT REALLY OUR PURVIEW. I THINK WE MADE THAT DECISION  
5 ALREADY, BUT JUST TO REITERATE THAT.

6 CHAIRMAN LO: IT NEEDS TO BE OVERSEEN, BUT  
7 THAT'S THE RESPONSIBILITY FOR THE LEGISLATURE AND OTHER  
8 REGULATORY AGENCIES. OUR MANDATE IS TO LOOK AFTER  
9 CIRM-FUNDED RESEARCH. AND AS WE HAVE SAID BEFORE,  
10 THERE'S STRONG REASONS NOT TO TRY AND OVERSTEP OUR  
11 AUTHORITY.

12 MR. SHEEHY: WE WOULD WELCOME THE LEGISLATURE  
13 DOING AND TAKING OVERSIGHT.

14 CHAIRMAN LO: PUBLIC COMMENTS? I KNOW WE  
15 HAVE SEVERAL.

16 MR. SIMPSON: JOHN SIMPSON FROM THE  
17 FOUNDATION FOR TAXPAYER AND CONSUMERS RIGHTS. IS THAT  
18 WORKING? I GUESS I WOULD HAVE TO AGREE WITH ZACH, THAT  
19 IF YOU ADOPTED ALL OF THESE TODAY, I WOULD SORT OF  
20 SCRATCH MY HEAD. THEY'RE OFFERED AS SERIOUS POINTS FOR  
21 CONSIDERATION. ALSO, I TAKE THE POINT THAT ALL OF THE  
22 POLICIES ARE GOING TO BE COMING TOGETHER IN ONE MASSIVE  
23 DOCUMENT. THE REASON I OFFER THESE HERE IS BECAUSE YOU  
24 BRING UP THE ISSUE OF COMPLIANCE AND ALSO THE ISSUE OF  
25 RECORDKEEPING IN YOUR STANDARDS AND GUIDELINES THERE.

1                   WHETHER THESE FIND A WAY INTO, I GUESS,  
2                   WHAT'S BEING CALLED THE GAP POLICY OR WHERE IS  
3                   APPROPRIATE IS NOT ENTIRELY CLEAR TO ME AND MAY BECOME  
4                   CLEARER AS THE STRATEGIC PLAN DEVELOPS AND THE IP  
5                   POLICIES AND THAT SORT OF THING. BUT THERE ARE A  
6                   COUPLE OF POINTS I WANTED TO MAKE OVERARCHINGLY ON  
7                   THIS.

8                   A YEAR OR TWO AGO IF SOMEONE HAD SAID TO ME,  
9                   WELL, IF THE UNIVERSITIES ASSURE US THAT EVERYTHING IS  
10                  OKAY, HAVING COME FROM AN ACADEMIC FAMILY, I MIGHT HAVE  
11                  TENDED TO BELIEVE THAT, BUT I'M NOW WATCHING EVERYTHING  
12                  THAT'S UNFOLDING WITH THE UNIVERSITY OF CALIFORNIA AND  
13                  ITS SALARY PRACTICES WHERE APPARENTLY THEY'VE VIOLATED  
14                  ALL SORTS OF RULES AND REGULATIONS. AND EVEN THE  
15                  REGENTS HAVEN'T KNOWN ABOUT IT. AND THEY'RE NOW  
16                  FINDING THIS OUT THROUGH STATE AUDITS.

17                  THAT GOES TO THE POINT OF I THINK THERE NEEDS  
18                  TO BE AN INDEPENDENT THIRD-PARTY AUDITOR IN SOME OF  
19                  THESE THINGS. WE SEEM TO HAVE -- WHEN IT COMES TO  
20                  SOMETHING AS SIMPLE AS WHETHER THE UC'S CAN FOLLOW  
21                  THEIR OWN REGENTS' POLICIES ABOUT HOW THEY PAY THEIR  
22                  TOP OFFICIALS AND VIOLATING THEM, I HAVE SERIOUS  
23                  CONCERNS ABOUT WHETHER AN ASSURANCE FROM A PARTICULAR  
24                  UNIVERSITY CAN BE TAKEN AT FACE VALUE.

25                  I WOULD HAVE ONCE BELIEVED THAT, BUT THE

1 DEMONSTRATION RIGHT NOW SEEMS TO BE QUITE CLEAR THAT  
2 IT'S NOT. SO I WOULD ASK THAT THAT BE CONSIDERED WHEN  
3 YOU THINK ABOUT AUDITING AND RECORDING ANY OF THESE  
4 SORTS OF THINGS.

5 BEYOND THAT, AGAIN, THE PROVISIONS THAT WE  
6 SUGGESTED HERE DID EXEMPT IP FROM PUBLIC DISCLOSURE AND  
7 THINGS THAT WOULD AFFECT PRIVACY ISSUES, BUT I THINK  
8 OTHER THAN THAT, AS MUCH OF THE REPORTING THAT IS  
9 REQUIRED HAS TO BE PUBLIC DOCUMENTS. AND THEY SHOULD  
10 BE PUBLIC DOCUMENTS THAT ARE AVAILABLE EITHER WHEN  
11 THEY'RE FILED WITH CIRM OR AT THE PARTICULAR FOUNDATION  
12 OR RESEARCH INSTITUTION THAT ORIGINATES THEM. PUBLIC  
13 OUGHT TO BE ABLE TO GO IN THERE AND ASK TO SEE THEM.  
14 THANK YOU VERY MUCH.

15 CHAIRMAN LO: THANKS, JOHN. WE HAVE OTHER  
16 COMMENTS AS WELL.

17 MS. GREENFIELD: DEBORAH GREENFIELD WITH THE  
18 PRO-CHOICE ALLIANCE. TWO COMMENTS. I WOULD ADD THE  
19 UNIVERSITY OF PENNSYLVANIA AND GERALD SCHATTEN'S WORK  
20 THROUGH JOHN'S PREVIOUS COMMENTS.

21 BUT MORE IMPORTANTLY --

22 DR. HALL: UNIVERSITY OF PITTSBURGH. SET THE  
23 RECORD STRAIGHT HERE.

24 MS. GREENFIELD: I GUESS IT'S A PUBLIC  
25 UNIVERSITY. I'M NOT SURE. ANYWAYS, I WOULD ALSO ASK

1 YOU TO CONSIDER THE SPECIAL NATURE OF YOUR PARTICULAR  
2 MAKEUP OF THE COMMITTEE. I DON'T KNOW THE EXACT NATURE  
3 OF THE MAKEUP OF THE GRANTS COMMITTEE, BUT I THINK IN  
4 TERMS OF COMPLYING WITH ETHICAL STANDARDS, THE PEOPLE  
5 THAT HAVE BEEN CHOSEN SPECIFICALLY TO PROMULGATE THOSE  
6 STANDARDS, BECAUSE OF THEIR BACKGROUNDS AND THEIR  
7 POSITIONS, SHOULD BE MAKING THE DECISIONS REGARDING  
8 ENFORCEMENT BECAUSE THEY WILL HAVE THOSE SPECIFIC  
9 ETHICAL BACKGROUNDS OR AT LEAST SOME MEMBERS OF THE  
10 COMMITTEE COME ESPECIALLY TO THE COMMITTEE WITH THOSE  
11 BACKGROUNDS IN CHARGE. THANK YOU.

12 DR. HALL: LET ME JUST COMMENT ON THAT. I  
13 THINK THERE IS -- WE HAVE THE THREE WORKING GROUPS, AND  
14 THERE ARE SOMETIMES OVERLAPPING RESPONSIBILITY. AND WE  
15 WILL TRY TO WORK THESE OUT GOING FORWARD. AND I THINK  
16 THERE IS NO INTENT THAT THE GRANTS WORKING GROUP, AND I  
17 THINK THEY WOULD BE FIRST TO AGREE WITH THIS, WOULD BE  
18 OUR COURT OF FINAL DECISION ON ETHICAL MATTERS AND  
19 ETHICAL WRONGDOING. ON SCIENTIFIC ISSUES, WE WILL  
20 CONSULT WITH THEM. I THINK IF WE HAVE ETHICAL ISSUES  
21 OR THINGS THAT ARRIVE, IT IS MY BELIEF THAT THE PROPER  
22 PLACE IS TO COME BACK TO THIS WORKING GROUP JUST FOR  
23 THE REASONS THAT THE SPEAKER SAID.

24 MS. DELAURENTIS: SUSAN DELAURENTIS FROM THE  
25 ALLIANCE FOR STEM CELL RESEARCH. AND A NUMBER OF -- I

1 HAVE A NUMBER OF COMMENTS ABOUT A NUMBER OF THINGS, BUT  
2 LET ME START BY JUST EXPANDING ON SOMETHING THAT YOU  
3 HAVE JUST TALKED ABOUT, WHICH IS THAT YOU'RE NOT SORT  
4 OF THE POLICEMEN TO THE WORLD ABOUT WHAT'S HAPPENING  
5 WITH THE CIRM-FUNDED RESEARCH. BUT BESIDES THAT,  
6 THERE'S A LOT OF RESEARCH GOING ON THAT CIRM ISN'T  
7 FUNDING, AND HOW THAT ALL GETS WORKED OUT BETWEEN THE  
8 INSTITUTIONS, INSIDE THE INSTITUTIONS. I HAPPEN TO NOW  
9 BE ON AN ESCRO COMMITTEE. I'M ON THE ESCRO COMMITTEE  
10 AT UCLA, AND I HAVE ATTENDED TWO MEETINGS. AND THE  
11 COMPLICATIONS THAT WE'RE ALREADY DEALING WITH IN TERMS  
12 OF WHAT WILL HAPPEN WHEN THE CIRM FUNDING COMES AND HOW  
13 THAT WILL ALL WORK TOGETHER WITH THE FUNDING THAT'S  
14 ALREADY HAPPENED AND THE RESEARCH THAT'S ALREADY  
15 STARTED AND WHAT THE STANDARDS ARE GOING TO BE. AND I  
16 CAN TELL YOU RIGHT NOW THERE ARE GOING TO BE ALL KINDS  
17 OF ISSUES THAT ARE GOING TO BE BROUGHT BACK TO THIS  
18 COMMITTEE FROM THE PEOPLE THAT ARE ACTUALLY  
19 ON THE GROUND DOING THE WORK AND PUTTING THE STANDARDS  
20 INTO EFFECT THAT YOU ALL HAVE SPENT SO MUCH TIME  
21 DEALING WITH.

22 SO I WOULD URGE YOU TO JUST LET'S -- AS WE  
23 WERE SAYING, AS NIKE SAYS, JUST DO IT. LET THE SCIENCE  
24 BEGIN, AS THE *L.A. TIMES* EDITORIAL SAID LAST WEEK. YOU  
25 GUYS HAVE DONE AN AMAZING JOB. YOU'VE BEEN VERY

1 THOUGHTFUL. I THINK YOU'VE BENT OVER BACKWARDS TO  
2 LISTEN TO ALL OF THE CRITICISMS FROM THOSE WHO MAY NOT  
3 BE IN AGREEMENT WITH HOW YOU ARE DOING THINGS. BUT IN  
4 THE END, YOU HAVE TO MAKE THE BEST DECISIONS USING THE  
5 BEST INFORMATION THAT YOU HAVE NOW AND JUST DO IT.  
6 BECAUSE THERE ARE GOING TO BE SO MANY CHANGES AND SO  
7 MANY THINGS THAT ARE GOING TO HAPPEN THAT YOU'RE GOING  
8 TO BE FACED WITH ON AN ONGOING BASIS WITH THIS LIVING  
9 DOCUMENT AND WITH THIS PROCESS. AND SO I JUST  
10 ENCOURAGE YOU TO MOVE FORWARD AS QUICKLY AS POSSIBLE.

11 I WOULD ALSO JUST LIKE TO SAY I DON'T KNOW  
12 WHAT A LOT OF THESE CRITICS, WHAT'S THE WORST THING  
13 THAT'S GOING TO HAPPEN THAT EVERYONE IS SO CONCERNED  
14 ABOUT? THIS GOES THROUGH A LOT OF DIFFERENT THINGS,  
15 WHETHER IT'S LEGISLATIVELY OR WHAT YOU'RE DEALING WITH.  
16 I'M PARTICULARLY KIND OF IN A FURY ABOUT THAT, AND I  
17 WOULD LIKE TO KNOW WHAT IT IS THAT EVERYBODY THINKS IS  
18 GOING TO BE SO AWFUL THAT'S GOING TO HAPPEN IF WE DON'T  
19 CHANGE THINGS AND PUT ALL OF THESE THINGS INTO PLACE  
20 RIGHT NOW AND ADD ALL THESE OTHER LAYERS OF WORK AND  
21 BUREAUCRACY AND REPORTING. LET'S JUST DO IT.

22 CHAIRMAN LO: OKAY.

23 DR. PRIETO: IF I CAN RESPOND TO THAT. I  
24 THINK UNFORTUNATELY AND SADLY PROBABLY THE WORST THING  
25 THAT CAN HAPPEN IS WHAT WE SAW IN KOREA. I THINK



1 THAT'S THE CONCERN, BUT I THINK THE FEELING I'M GETTING  
2 FROM THIS DISCUSSION IS THAT MAYBE THIS COMMITTEE IS  
3 NOT THE PLACE TO DECIDE THE ENFORCEMENT MECHANISMS,  
4 THAT WE SHOULD PASS ON OUR FEELING THAT WE BELIEVE  
5 THERE NEEDS TO BE APPROPRIATE ENFORCEMENT. I THINK THE  
6 PLACE FOR THOSE TERMS IS IN THE GRANTS ADMINISTRATION  
7 POLICY.

8 ONE OF THE CONCERNS I HAVE AS AN ICOC MEMBER  
9 IS KNOWING THE STAFF CONSTRAINTS PLACED BY THE  
10 INITIATIVE ON CIRM. THERE ARE GOING TO HAVE TO BE SOME  
11 CREATIVE SOLUTIONS TO THAT POLICING BECAUSE CIRM CANNOT  
12 HIRE STAFF TO DO ALL OF THAT. BUT THAT, I THINK, IS  
13 NOT OUR PROBLEM OR OUR ISSUE FOR TODAY. I'M HOPING WE  
14 CAN MOVE ON.

15 DR. KIESSLING: I HAVE A SPECIFIC QUESTION.  
16 I DON'T KNOW EXACTLY WHO CAN ANSWER THIS. IF I WANTED  
17 FIND OUT, IF I WERE A MEMBER OF THE PUBLIC AND I WANTED  
18 TO FIND OUT WHAT KINDS OF HUMAN SUBJECTS RESEARCH WERE  
19 GOING ON RIGHT NOW AT ONE OF THE MAJOR HOSPITALS, COULD  
20 I DO THAT? COULD I JUST GO TO THEIR IRB AND GET A LIST  
21 OF WHAT PROJECTS ARE ONGOING? IS THAT PUBLIC?

22 DR. HALL: AS FAR AS I KNOW, ANN, AT THE  
23 UNIVERSITY OF CALIFORNIA I THINK YOU COULD.

24 DR. KIESSLING: I CAN JUST WALK INTO THE IRB  
25 OFFICE AND SAY I'D LIKE TO SEE WHAT'S GOING ON?

1 DR. HALL: YOU'D HAVE TO IDENTIFY YOURSELF.  
2 I'M NOT QUITE SURE. BUT I THINK, PARTICULARLY IF IT  
3 WERE TO GO THROUGH FOIA, I'M SURE THOSE RECORDS ARE  
4 AVAILABLE. THE LIST OF PROJECTS THAT ARE GOING ON I  
5 THINK IS AVAILABLE. I'M NOT SURE THE MATTER OF THE  
6 MATERIAL THAT IS CONFIDENTIAL, AS YOU KNOW. BUT A LIST  
7 OF THE MATTER IS AVAILABLE, AND I THINK IT'S A MATTER  
8 OF PUBLIC INFORMATION. I DON'T KNOW FOR PRIVATE  
9 UNIVERSITIES, I DON'T HAVE THAT EXPERIENCE, BUT  
10 CERTAINLY FOR NIH-FUNDED RESEARCH, THAT IS PUBLIC  
11 INFORMATION.

12 DR. KIESSLING: I KNOW THAT. ARE WE BEING  
13 ASKED TO HOLD TO A HIGHER STANDARD HERE THAN IS  
14 CURRENTLY FOR HUMAN SUBJECTS RESEARCH?

15 DR. HALL: ANYTHING THAT IS CIRM-FUNDED WILL  
16 BE A MATTER OF PUBLIC RECORD. THERE'S NO QUESTION  
17 ABOUT THAT. AND IT WILL -- THOSE, IN ORDER TO BE  
18 FUNDED, IT WILL HAVE TO BE APPROVED OR HAVE GONE  
19 THROUGH THE ESCRO'S AND HAVE IRB APPROVAL WHERE  
20 APPROPRIATE OR HAVE THE ANIMAL COMMITTEE APPROVAL WHERE  
21 APPROPRIATE AND A WHOLE BUNCH OF OTHER REGULATORY  
22 MATTERS. SO I THINK THAT INFORMATION WILL BE CERTAINLY  
23 AVAILABLE TO ANYBODY WHO WANTS IT. I DON'T THINK  
24 THERE'S ANY PROBLEM ABOUT GETTING THAT INFORMATION.  
25 THAT IS, THAT IT WILL HAVE PASSED THOSE COMMITTEES.

1                   FOR REASONS THAT I THINK WE ALL UNDERSTAND,  
2                   DELIBERATIONS OF THOSE COMMITTEES ARE NOT PUBLIC,  
3                   ALTHOUGH I SIMPLY DON'T KNOW. I SUSPECT THE FINAL  
4                   REPORTS THAT THEY MAKE ARE.

5                   BERNIE, YOU MAY KNOW MORE ABOUT THAT THAN I  
6                   DO OR ROB TAYLOR.

7                   CHAIRMAN LO: ACTUALLY WE JUST WENT THROUGH  
8                   THIS. I THINK ZACH'S ABSOLUTELY RIGHT. THE LISTING OF  
9                   THE TITLES OF THE PROTOCOLS THAT THE IRB HAS APPROVED  
10                  IS READILY AVAILABLE TO THE PUBLIC. I DON'T THINK YOU  
11                  CAN GET THE PROTOCOLS THAT WERE SUBMITTED AND NOT  
12                  APPROVED. THERE ARE CONFIDENTIALITY AND PATIENT  
13                  CONFIDENTIALITY, SUBJECT CONFIDENTIALITY, AND  
14                  INTELLECTUAL PROPERTY RESTRICTIONS. IF SOMEONE COMES  
15                  AND REQUESTS THE MINUTES FROM IRB, THEY WILL BE MADE  
16                  AVAILABLE AFTER REDACTION BY THE LEGAL AFFAIRS OFFICE  
17                  TO MAKE SURE THAT WE PROTECT THE CONFIDENTIALITY OF THE  
18                  PARTICIPANTS AND TRADE SECRETS. SO THE SUMMARY OF THE  
19                  MINUTES WOULD BE AVAILABLE, AGAIN FOR A PUBLIC  
20                  INSTITUTION.

21                  MS. DELAURENTIS: I WAS JUST GOING TO SAY THE  
22                  MINUTES FROM THE ESCRO, I KNOW, AT UCLA ARE AVAILABLE,  
23                  BUT IT'S THROUGH THE FREEDOM OF INFORMATION ACT. SO  
24                  THE MINUTES OF THE MEETINGS THAT I ATTEND WILL BE  
25                  AVAILABLE.

1                   CHAIRMAN LO:  WHAT THE SITUATION IS FOR  
2 PRIVATE UNIVERSITIES OR FOR-PROFIT ENTITIES THAT MAY BE  
3 FUNDED IS A QUESTION.  I THINK, AGAIN, MY SENSE IS THAT  
4 WE HAVE SET THE TONE, WE'VE SORT OF SECONDED ZACH'S  
5 COMMITMENT TO HAVING AN EFFECTIVE POLICY FOR  
6 RECORDKEEPING AND OVERSIGHT, AND THAT WILL BE WORKED  
7 OUT AND WILL BE AVAILABLE.  I THINK THAT THEY ARE GOING  
8 TO BE OPEN TO THE SUGGESTIONS THAT HAVE BEEN MADE IN  
9 THE FORMAL COMMENTS TO US, AND ALSO I THINK -- I THINK  
10 I CAN SPEAK FOR THESE GROUPS THAT CARE VERY MUCH ABOUT  
11 THIS, THAT WE WILL FOLLOW THE SUBSEQUENT STEPS OF THE  
12 GRANTS WORKING GROUP.

13                   DR. HALL:  CAN I JUST MAKE A COMMENT, IF I  
14 MIGHT, BERNIE, JUST TO UNDERLINE SOMETHING SUSAN SAID.  
15 I APPRECIATE HER EXPRESSING THIS POINT OF VIEW AS A  
16 MEMBER OF AN ESCRO.  IMPLEMENTING THE WORK OF THIS  
17 COMMITTEE AND, IN FACT, THE CIRM POLICIES IN GENERAL IS  
18 GOING TO BE A HUGE UNDERTAKING.  AND MANY OF THE  
19 INSTITUTIONS ARE THERE WAITING AND WONDERING WHAT IT IS  
20 WE'RE GOING TO REQUIRE.  THEY WILL WANT TO KNOW WHAT WE  
21 MEAN BY THIS AND WHAT WE MEAN BY THAT.  AND SO THAT IS  
22 GOING TO BE AN ENORMOUS JOB THAT WE HAVE AS THIS WHOLE  
23 UNDERTAKING GETS UNDERWAY.  I THINK IT IS THAT JOB OF  
24 IMPLEMENTATION THAT WILL BE AS IMPORTANT IN ASSURING  
25 THAT THINGS GET DONE WELL AND THAT ALL THE RULES ARE

1 FOLLOWED AS MUCH AS ANYTHING ELSE. THAT IS, OUR  
2 ABILITY TO MAKE CLEAR WHAT WE MEAN BY THESE TO FORM  
3 EFFECTIVE WORKING RELATIONSHIPS WITH THESE INSTITUTIONS  
4 AND TO BE ABLE TO ASSURE OURSELVES THAT MECHANISMS ARE  
5 IN PLACE AS WE GO ALONG THAT WILL BE EFFECTIVE.

6 BUT THE AMOUNT OF WORK ON MANY, MANY PEOPLE'S  
7 PARTS THAT WILL BE NECESSARY TO TURN THIS ENTIRE THING  
8 INTO OPERATION, THAT IS, TO GET IT ROLLING AT AN  
9 INSTITUTIONAL LEVEL, SHOULD NOT BE UNDERESTIMATED. AND  
10 I THINK EVEN SMALL MOVEMENTS BY THIS GROUP WILL HAVE  
11 VERY LARGE IMPLICATIONS FOR THOSE INSTITUTIONS. SO I  
12 THINK IT'S USEFUL TO BEAR THAT IN MIND, AND I SEE IT AS  
13 A WAY -- THAT IS, I SEE AS MUCH DAMAGE POTENTIALLY DONE  
14 NOT BY WILLFUL INTENT, BUT SIMPLY BY CONFUSION AND BY  
15 LACK OF CLARITY AND BY SORT OF GETTING ANYTHING LIKE  
16 THAT STARTED. SO IT'S A CHALLENGE WE WILL FACE AS BEST  
17 WE CAN.

18 CHAIRMAN LO: MY SENSE IS THAT WE'VE REACHED  
19 CLOSURE ON THIS ISSUE AND WE'LL CONTINUE TO ADDRESS IT.  
20 I'D LIKE TO MOVE ON TO A COUPLE OTHER ISSUES THAT ARE  
21 IMPORTANT THAT I'D LIKE TO ADDRESS. WE'RE GOING TO  
22 COME BACK TO THE ISSUE WE TALKED ABOUT BEFORE LUNCH  
23 WHEN SHERRY COMES BACK AFTER A CONFLICTING OBLIGATION.  
24 SHE'LL BE BACK AROUND THREE.

25 ONE TOPIC THAT WAS RAISED IN THE PUBLIC

1 COMMENTS THAT I THINK WE DO NEED TO ADDRESS IS THE  
2 QUESTION OF INHERITABLE GENETIC MODIFICATIONS. AGAIN,  
3 THE COMPOSITE OF COMMENTS THAT WE WERE UNABLE TO  
4 SUMMARIZE ON PAGE 3, AND THIS IS THE ONE THAT STARTS  
5 WITH THE COVER LETTER FROM GEOFF. PAGE 3, THESE ARE  
6 COMMENTS FROM THE PRO-CHOICE ALLIANCE FOR RESPONSIBLE  
7 RESEARCH AND THE CENTER FOR GENETICS AND SOCIETY. AT  
8 THE TOP OF PAGE 3, THEY MAKE TWO SUGGESTIONS.

9 ONE, THAT CIRM NOT FUND TWO DIFFERENT TYPES  
10 OF RESEARCH. F, TRANSFER OF A GENETICALLY MODIFIED  
11 NUCLEUS OR STEM CELL OR ARTIFICIAL CHROMOSOME INTO A  
12 HUMAN OOCYTE OR EMBRYO.

13 AND, G, THE GENETIC ALTERATION OF A HUMAN  
14 EMBRYO. THIS ADDRESSES THE POINT THAT WE DO NOT --  
15 THERE'S BEEN CONCERNS ABOUT DOING GENETIC MANIPULATION  
16 OF WHAT WILL BECOME STEM CELLS AND PASSING ON A GENETIC  
17 MODIFICATION TO FUTURE GENERATIONS AND THE SUBSEQUENT  
18 RISKS THAT THAT MAY POSE.

19 ALTA CHARO VERY SAGELY POINTED OUT THAT WE  
20 ALREADY HAVE IN OUR PROPOSED REGULATIONS THAT THE ICOC  
21 APPROVED A PROHIBITION ON CIRM FUNDING OF TRANSFER OF A  
22 HUMAN STEM CELL INTO A HUMAN EMBRYO.

23 MS. CHARO: OF ANY STEM CELL.

24 CHAIRMAN LO: OF ANY STEM CELL, HUMAN OR  
25 ANIMAL, INTO A HUMAN EMBRYO. SO THAT TAKES CARE OF

1 PART OF F, BUT NOT ALL OF IT.

2 I GUESS THE ISSUE THAT IS BEING POSED TO US  
3 IS WHETHER ON THE SAME KIND OF ETHICAL FOUNDATION WE  
4 WANT TO EXTEND OR TO RESTRICT OR FORBID CIRM FUNDING  
5 FOR OTHER ACTIVITIES THAT WOULD BASICALLY DO GERM LINE  
6 GENETIC MANIPULATION.

7 DR. PETERS: COULD I JUST BE CLEAR ON WHAT  
8 YOU'RE CALLING THE ETHICAL FOUNDATION? IS IT THE SAME  
9 THING THAT LEADS US TO PROSCRIBE GERM LINE  
10 INTERVENTION, OR IS IT A DIFFERENT ISSUE?

11 CHAIRMAN LO: I THINK IT IS THAT SAME SET OF  
12 CONCERNS THAT GO TO GERM LINE MANIPULATION.

13 DR. PETERS: THANKS.

14 CHAIRMAN LO: THOUGHTS ON THAT ONE WAY OR THE  
15 OTHER?

16 DR. TAYLOR: IT'S KIND OF UNFORTUNATE THAT  
17 KEVIN IS NOT -- KEVIN, YOU OUT THERE?

18 DR. EGGAN: I'M HERE.

19 DR. TAYLOR: SO HERE'S THE QUESTION THAT  
20 MAYBE YOU AND ANN CAN HELP ME WITH. I'VE BEEN READING  
21 SOME OF THOSE JONATHAN TILLY PAPERS AND SOME OF THE  
22 DISCUSSION ABOUT THOSE AND SCRATCHING MY HEAD A LITTLE  
23 BIT. ARE WE GOING TO NEED TO POTENTIALLY WORRY ABOUT  
24 STEM CELL THERAPIES ENTERING THE GERM LINE EVEN WHEN  
25 WE'RE NOT EXPECTING IT? HIS DATA IN THAT MOUSE MODEL

1 SUGGESTED THAT A BONE MARROW TRANSPLANT, WHICH I  
2 BELIEVE HAS NEVER BEEN SEEN IN ANY HUMAN CONDITIONS,  
3 BUT THAT BONE MARROW TRANSPLANTS INTO MICE WITH THEIR  
4 OVARIES ABLATED EITHER GENETICALLY OR BY RADIATION  
5 COULD ACTUALLY REPOPULATE OOCYTES WITHIN THE OVARY.

6 SO I THINK WE ALWAYS THOUGHT THAT WAS GOING  
7 TO BE ESSENTIALLY IMPOSSIBLE TO ACHIEVE, EVEN THOSE OF  
8 US WHO WANTED TO TRY TO TREAT PREMATURE OVARIAN  
9 FAILURE, FOR EXAMPLE. I'M WONDERING NOW WHETHER  
10 NONTARGETED -- WHETHER STEM CELL THERAPIES MIGHT  
11 POTENTIALLY TARGET THE GERM LINE EVEN WHEN WE AREN'T  
12 INTENDING TO DO SO.

13 DR. EGGAN: I CAN SPEAK DIRECTLY TO THIS,  
14 ALTHOUGH IT'S DIFFICULT FOR ME TO DO SO FOR A NUMBER OF  
15 REASONS. BUT WHAT I WOULD SAY IS THAT I HAVE GOOD  
16 REASON TO BELIEVE THAT WE SHOULDN'T WORRY ABOUT THE  
17 DATA IN THOSE PAPERS. I WISH I COULD DO BETTER THAN  
18 THAT, BUT I CAN'T.

19 DR. TAYLOR: THAT'S PERFECT. THANK YOU.

20 DR. EGGAN: I WILL JUST SAY THAT I AM AWARE  
21 OF EXPERIMENTS WHICH SUGGESTED THE RESULTS IN THOSE  
22 EXPERIMENTS ARE NOT CORRECT, AND THAT THERE IS NO  
23 REASON TO BELIEVE THAT BONE MARROW PERIPHERAL BLOOD  
24 CELLS IN THE CIRCULATION CONTRIBUTE TO A  
25 PHYSIOLOGICALLY RELEVANT POOL OF OOCYTES IN ANIMALS.



1 DR. PRIETO: DO YOU THINK THAT THIS  
2 CONCEIVABLY COULD OCCUR IN THE FUTURE?

3 DR. EGGAN: NO.

4 CHAIRMAN LO: COULD I ALSO ASK KEVIN AND ANN  
5 AS WELL. IS THE KIND OF PROHIBITION ON CIRM FUNDING  
6 THAT'S BEING SUGGESTED IN F AND G, TOP OF THE PAGE, IS  
7 THAT LIKELY TO CLOSE OFF IMPORTANT RESEARCH THAT DOES  
8 NOT RAISE THE KINDS OF ETHICAL ISSUES THAT ONE THINKS  
9 ABOUT IN TERMS OF GERM LINE MANIPULATION?

10 DR. KIESSLING: CAN I ASK A SIDE QUESTION TO  
11 THAT? THE POINT OF G WOULD BE TO NOT GENETICALLY ALTER  
12 A HUMAN EMBRYO THAT YOU PLAN TO TRANSFER BACK INTO A  
13 UTERUS, RIGHT, BECAUSE HOPEFULLY WE'RE GOING TO GET  
14 BETTER AND BETTER AT DERIVING STEM CELLS FROM HUMAN  
15 EMBRYOS, AND GENETICALLY MODIFYING THEM MIGHT IMPROVE  
16 THAT. SO FOR A LABORATORY MANIPULATION, I DON'T SEE  
17 THAT G IS NECESSARY. IF THE GOAL IS TO NOT THEN  
18 TRANSFER IT BACK INTO A UTERUS, I DON'T HAVE ANY  
19 PROBLEMS WITH THAT. I DON'T KNOW ABOUT YOU, KEVIN, BUT  
20 I CAN'T IMAGINE THAT YOU'D WANT TO GENETICALLY ENGINEER  
21 SOMETHING AND THEN TRANSFER IT BACK INTO A UTERUS  
22 ANYWAY.

23 DR. EGGAN: NO, I CAN'T THINK. I MEAN  
24 BASICALLY ALMOST EVERYTHING THAT WE'RE DOING IS  
25 PROHIBITING TRANSFERRING THEM INTO EMBRYOS AT ALL AND

1 BACK INTO THE UTERUS. I DON'T SEE THAT AS BEING AN  
2 ISSUE. I DO THINK WE HAVE TO BE CAREFUL TO QUALIFY THE  
3 LANGUAGE SUCH THAT WE DON'T, AS ANN POINTS OUT,  
4 INADVERTENTLY PROHIBIT THINGS THAT WE WOULDN'T WANT TO  
5 DO. FOR INSTANCE, I CAN SAY WITH SOME CERTAINTY THAT  
6 PEOPLE WILL WANT TO DO SOMATIC CELL NUCLEAR  
7 TRANSPLANTATION WITH TRANSGENIC HUMAN CELLS.

8 MS. CHARO: WITH WHAT?

9 DR. EGGAN: WITH TRANSGENIC HUMAN CELLS. SO,  
10 FOR INSTANCE, YOU COULD IMAGINE THAT SOMEONE WHO WANTS  
11 TO MAKE A PATIENT-SPECIFIC EMBRYONIC STEM CELL LINE  
12 FROM A PATIENT WITH DIABETES MIGHT OPT TO INTRODUCE  
13 SOME GENE INTO THAT SOMATIC CELL BEFORE THE NUCLEAR  
14 TRANSPLANTATION. SO YOU WOULD IN A SENSE MAKE IN THAT  
15 SITUATION A TRANSGENIC PREIMPLANTATION HUMAN EMBRYO.  
16 IT'S TRUE THAT THERE ARE CELLS WITHIN AN EMBRYO WHICH  
17 HAVE THE CAPACITY TO CONTRIBUTE TO THE GERM LINE, BUT,  
18 AGAIN, THE INTENTION IS NOT TO MAKE A PERSON WHICH  
19 CARRIES THAT GERM LINE MUTATION AND TO MAKE AN  
20 EMBRYONIC STEM CELL LINE WHICH HAS THAT GENETIC CHANGE.

21 SO WHATEVER LANGUAGE IS CRAFTED HAS TO TAKE  
22 THINGS LIKE THAT INTO CONSIDERATION.

23 CHAIRMAN LO: SO BASICALLY, KEVIN, YOU'RE  
24 POINTING THAT F AS WRITTEN WOULD PRECLUDE THAT LINE OF  
25 RESEARCH, WHICH SOUNDS LIKE WE WOULD NOT WANT TO

1 PRECLUDE IT AS LONG AS THE RESULTANT EXPERIMENT ISN'T  
2 USED FOR REPRODUCTIVE PURPOSES. I THINK WE PUT OUR  
3 FINGER ON THE ETHICAL CONCERNS REALLY HAVE TO DEAL WITH  
4 CREATING A HUMAN BEING WITH THAT GENETIC MODIFICATION  
5 IN THE NEXT GENERATION, BUT WE WOULD NOT WANT TO EXTEND  
6 THE PROHIBITION TO IN VITRO WORK THAT COULD ACTUALLY BE  
7 USEFUL FOR MECHANISMS LEADING TO POTENTIAL THERAPIES.

8 DR. KIESSLING: SO BOTH F AND G PROBLEM WILL  
9 BE PROBLEMATIC TO LIMIT THE KINDS OF STEM CELLS YOU CAN  
10 DERIVE FROM EGGS.

11 CHAIRMAN LO: SO WOULD YOU -- IF WE PUT IN A  
12 QUALIFIER, THAT NOT ELIGIBLE FOR FUNDING WOULD BE ONLY  
13 IF THE RESULTS WOULD BE USED FOR -- SOUNDS LIKE WE  
14 NEED TO HAVE -- IF WE WANT TO DO SOMETHING ALONG THE  
15 LINES OF F AND G, WE NEED TO PUT A QUALIFIER IN THAT IS  
16 ONLY WITH THE RESULT OF THE MANIPULATION.

17 DR. HALL: BERNIE, CAN YOU HELP US? WHERE IS  
18 F AND G?

19 CHAIRMAN LO: IT'S PAGE 3 OF GEOFF'S SUMMARY  
20 E-MAIL THAT'S -- IT'S FROM THE PRO-CHOICE ALLIANCE FOR  
21 RESPONSIBLE RESEARCH AND CENTER FOR GENETICS AND  
22 SOCIETY.

23 DR. HALL: OKAY.

24 CHAIRMAN LO: IT'S PAGE OF 3 OF THEIR  
25 NUMBERING.

1 DR. HALL: F AND G, GOT IT.

2 CHAIRMAN LO: OKAY. SO BASICALLY IT SOUNDS  
3 LIKE WE'RE SEEMING TO AGREE THAT IF THE RESULTING  
4 EMBRYO OR PRODUCT OF THAT SCNT WOULD BE USED FOR  
5 REPRODUCTIVE PURPOSES, THAT WE WOULD NOT WANT TO  
6 COUNTENANCE.

7 DR. PETERS: WE SAID FOR REPRODUCTIVE  
8 PURPOSES.

9 DR. EGGAN: I HAVE TO SAY THAT AS I READ  
10 THESE IN THIS CONTEXT AND THE WAY THAT THIS IS COUCHED,  
11 I DON'T THINK THAT EITHER OF THESE STATEMENTS ARE  
12 APPROPRIATE AND SHOULD BE SUPPORTED OR ENDORSED BY THIS  
13 COMMITTEE.

14 DR. KIESSLING: RIGHT. RIGHT. BUT DON'T WE  
15 HAVE THIS COVERED? I MEAN WE HAVE A LOT OF LANGUAGE  
16 THAT PROHIBITS CLONING FOR HUMAN REPRODUCTIVE PURPOSES.

17 CHAIRMAN LO: REPRODUCTIVE CLONING. SO THAT  
18 TAKES CARE OF THAT. WE ALSO HAVE LANGUAGE THAT  
19 PROHIBITS TRANSPLANTATION OF ANY STEM CELL INTO A HUMAN  
20 EMBRYO. SO THAT PRECLUDES THAT.

21 DR. KIESSLING: I THINK THESE TWO ARE BOTH  
22 COVERED.

23 CHAIRMAN LO: WHAT WE DON'T HAVE COVERED ARE  
24 THE GENETIC MANIPULATION --

25 MS. CHARO: I THINK ACTUALLY IT WAS KIND OF

1 SAID AROUND THE TABLE. AND, KEVIN, I'D BE VERY  
2 INTERESTED IN YOUR REACTION AS WELL AS ANN'S HERE. IS  
3 THERE ANY REASON NOT TO SAY EXPLICITLY THAT AMONG THE  
4 ACTIVITIES NOT ELIGIBLE FOR CIRM FUNDING IS THE  
5 TRANSFER INTO A UTERUS OF ANY HUMAN EMBRYO THAT HAS  
6 BEEN SUBJECT TO GENETIC OR STEM CELL MANIPULATION?

7 DR. KIESSLING: RIGHT. THAT'S FINE.

8 MS. CHARO: BECAUSE THEN WE CAN SIMPLY SAY  
9 CIRM FUNDING ISN'T AVAILABLE IF YOU'RE GOING TO  
10 TRANSFER A HUMAN EMBRYO THAT'S BEEN MANIPULATED INTO A  
11 UTERUS. I DIDN'T HEAR ANYBODY THINK THAT THAT SHOULD  
12 BE FUNDED, RIGHT?

13 DR. PRIETO: IT SEEMS TO ME WHEN I THINK  
14 ABOUT SOME OF THIS, THAT WE'VE STEPPED INTO STAR TREK  
15 HERE. BUT, YOU KNOW, I CAN CONCEIVE OF SITUATIONS IN  
16 THE DISTANT FUTURE OF PRENATAL DIAGNOSIS OF GENETIC  
17 DISEASES WHERE CURRENTLY THEY CAN BE DIAGNOSED AND THE  
18 ONLY SOLUTION, SO TO SPEAK, IS TO TERMINATE THE  
19 PREGNANCY. AND IN THE FUTURE GENETIC MANIPULATION,  
20 REPLACEMENT OF A DEFECTIVE GENE WITH A NORMAL GENE,  
21 WOULD INSTEAD ALLOW DEVELOPMENT OF A NORMAL EMBRYO.

22 MS. CHARO: FRANCISCO, THIS IS EXACTLY WHERE  
23 THE CONVERSATION ABOUT GERM LINE THERAPY HAS GONE IN  
24 THE LAST YEAR OR SO. YOU SEE ARTICLES BUBBLING UP NOW  
25 IN THE LITERATURE WHERE THERE'S BEEN A KIND OF BROADLY

1 HELD CONSENSUS THAT WE DIDN'T KNOW HOW TO EVALUATE THE  
2 RISKS WELL ENOUGH IS NOW BEGINNING TO YIELD LITERATURE  
3 SAYING ARE WE READY. BERNIE HAS SERVED FOR MANY YEARS  
4 ON THE NIH RECOMBINANT DNA ADVISORY COMMITTEE, WHICH  
5 WAS TASKED IN PART WITH ANTICIPATING EXACTLY THIS  
6 QUESTION.

7 SO I GUESS THE ISSUE HERE WOULD BE WHETHER IT  
8 MAKES SENSE TO PUT SOMETHING LIKE FUNDING RESTRICTIONS,  
9 NOT THAT PEOPLE CAN'T DO IT, IT'S THAT WE WON'T FUND IT  
10 HERE EXPLICITLY FOR THE SAKE OF COMFORT LEVELS, OR TO  
11 SIMPLY TRUST THE GRANTING GROUPS TO NOT DO THIS UNLESS  
12 AND UNTIL THERE IS A CONSENSUS IN THE FIELD THAT PEOPLE  
13 UNDERSTAND HOW TO EVALUATE THE PROPOSED RESEARCH.

14 DR. PRIETO: I SAY MY GUT FEELING IS WE'RE  
15 NOT READY.

16 CHAIRMAN LO: I THINK WE CAN PUT IN A  
17 QUALIFIER "AT THIS TIME."

18 DR. EGGAN: BERNIE, I'D ACTUALLY LIKE TO  
19 STRONGLY INTERJECT AT THIS MAKE AND MAKE THE FOLLOWING  
20 STATEMENT. AND THAT IS, SUPPOSE IT ENDS UP BEING QUITE  
21 DIFFICULT TO PRODUCE EMBRYONIC STEM CELL LINES BY  
22 NUCLEAR TRANSPLANTATION, BUT WE SUPPOSE THAT IF WE  
23 COULD OVEREXPRESS SOME GENE WHICH IS IMPORTANT FOR  
24 EMBRYONIC STEM CELLS INTO SOMATIC CELLS BEFORE WE DID  
25 NUCLEAR TRANSPLANTATION AND THAT WOULD MAKE THE

1 DERIVATION OF THOSE ES CELLS MORE EFFICIENT, WOULDN'T  
2 WE WANT TO DO THAT, AND WOULDN'T THAT BE CREATING A  
3 TRANSGENIC HUMAN EMBRYO?

4 MS. CHARO: YES. BUT, KEVIN, THE PROPOSAL  
5 HERE IS JUST TO NOT FUND ANYTHING THAT INVOLVES  
6 TRANSFERRING SUCH AN EMBRYO INTO A UTERUS.

7 DR. EGGAN: OKAY. GREAT. I'M SORRY. THAT  
8 WAS NOT CLEAR TO ME.

9 CHAIRMAN LO: THAT'S THE POINT THAT WE'RE  
10 TRYING TO CENTER ON. FOR RESEARCH WE'RE GOING TO ALLOW  
11 IT FOR RESEARCH PURPOSES, BUT NOT FOR REPRODUCTIVE  
12 PURPOSES. AND WE PUT THE QUALIFIER "AT THIS TIME" FOR  
13 THE REPRODUCTIVE PURPOSES TO LEAVE OPEN A POSSIBILITY  
14 FOR FUTURE GENETIC CORRECTION OF CONDITIONS DIAGNOSED  
15 THROUGH PGD.

16 DR. TAYLOR: I GUESS THAT WOULD BE THE POINT  
17 THAT I'D WANT TO EMPHASIZE. THERE ARE SORT OF THREE  
18 OUTCOMES. THERE'S REPRODUCTIVE REASONS, THERE'S  
19 RESEARCH REASONS, AND THERE'S ESSENTIALLY GENE THERAPY  
20 REASONS THAT COULD BE USED FOR THERAPEUTIC PURPOSES,  
21 AND WE CERTAINLY DON'T WANT TO LOSE THAT LATTER OPTION.  
22 RIGHT NOW AS WRITTEN, F WOULD COMPLETELY WIPE THAT OUT  
23 IF WE WERE TO ADOPT THAT LANGUAGE.

24 MS. CHARO: NOW, JUST BECAUSE ONCE WE MAKE  
25 ONE CHANGE, IT'S ALWAYS LIKE PULLING A THREAD ON THE

1 RUG. IT'S VERY DANGEROUS. SO IF WE TAKE A LOOK AT THE  
2 EXISTING REGS THAT WE NOW HAVE POSTED FOR COMMENT AND  
3 LOOK, FOR EXAMPLE, AT C AND D, WHICH SAID NO CIRM  
4 FUNDING IF YOU INTRODUCE BASICALLY HUMAN STEM CELLS  
5 INTO PRIMATE EMBRYOS OR ANY KIND OF STEM CELL INTO A  
6 HUMAN EMBRYO. WE DIDN'T TALK ABOUT MAKING THIS A  
7 FUNDING RESTRICTION WITH REGARD TO THEN TRANSPLANTING  
8 THOSE EMBRYOS INTO A UTERUS. IT WAS A BLANKET  
9 RESTRICTION, RIGHT.

10 IN OTHER WORDS, HERE WE'RE TALKING NOW ABOUT  
11 SOMETHING WITH REGARD TO GENETIC MANIPULATION OF  
12 EMBRYOS THAT IS LOOSER THAN THE VERY REGS THAT WE NOW  
13 HAVE, WHICH DO A BASIC PROHIBITION ON MANIPULATING  
14 THESE EMBRYOS AT ALL REGARDLESS OF WHETHER THEY WOULD  
15 ULTIMATELY BE INTRODUCED INTO A UTERUS.

16 SO WE ARE SETTING OURSELVES UP FOR SOME  
17 DEGREE OF INCONSISTENCY, AND I JUST WANTED TO NOTE IT  
18 IN CASE PEOPLE WANT TO DEAL WITH IT. IT'S ATTRACTED  
19 ATTENTION FROM PEOPLE WHO HAVE BEEN CRITIQUING THE NAS  
20 GUIDELINES. THERE ARE SCIENTISTS THAT HAVE ASKED WHAT  
21 THE PURPOSE IS OF, IN THE NAS GUIDELINES, A SUGGESTED  
22 PROHIBITION OR SELF-REGULATORY PROHIBITION ON SOMETHING  
23 THAT, ABSENT TRANSFER TO A UTERUS, COULD HAVE NO  
24 REPRODUCTIVE OUTCOME. SO THEY'VE BEEN ASKING WHY SO  
25 NARROW A SET OF RULES OUT OF THE NAS. AND SO WE'RE NOW



1 DISCUSSING EXACTLY THAT ISSUE THAT THEY HAVE BEEN  
2 DEBATING OUT THERE IN THE FIELD.

3 CHAIRMAN LO: ALTA, IS YOUR SUGGESTION THAT  
4 IF WE ADOPT OUR MODIFIED VERSIONS OF WHAT WE'VE  
5 PROPOSED INSTEAD OF F AND G, THAT WE THEN NEED TO GO  
6 BACK TO B AND C TO TALK ABOUT HAVING PROHIBITION ON  
7 CIRM FUNDING BE ONLY RESTRICTED TO TRANSFERRING TO  
8 UTERO AND TO ALLOW -- TO LEAVE OPEN THE POSSIBILITY OF  
9 CIRM FUNDING FOR IN VITRO RESEARCH?

10 MS. CHARO: RIGHT. IT'S ACTUALLY C AND D,  
11 NOT B AND C. YEAH. IT'S WORTH ASKING DO WE WANT THE  
12 THREE AREAS TO BE CONSISTENT WITH ONE ANOTHER. IF SO,  
13 WHAT ARE WE GOING TO PICK? THE PROHIBITION ON THE  
14 MANIPULATION OF THE EMBRYO PER SE OR THE PROHIBITION ON  
15 THE TRANSFER OF A MANIPULATED EMBRYO INTO A UTERUS? OR  
16 WE CAN LEAVE THEM INCONSISTENT. THAT'S ANOTHER CHOICE.  
17 I JUST WANT TO HIGHLIGHT IT.

18 CHAIRMAN LO: YOUR SUGGESTION?

19 MS. CHARO: MY SUGGESTION IS WE ASK KEVIN.

20 CHAIRMAN LO: KEVIN, ARE YOU STILL THERE?

21 DR. EGGAN: YES, I'M STILL HERE, BUT IT'S NOT  
22 CLEAR TO ME WHAT THE QUESTION FOR ME IS.

23 CHAIRMAN LO: OKAY. SO ALTA IS TALKING ABOUT  
24 IF WE GO TO 100300 IN WHAT WE NOW HAVE OUT FOR PUBLIC  
25 COMMENT, ACTIVITIES NOT ELIGIBLE FOR CIRM FUNDING, C

1 AND D TALK ABOUT THE INTRODUCTION OF STEM CELLS INTO  
2 NONHUMAN PRIMATE EMBRYOS AND THE INTRODUCTION OF ANY  
3 STEM CELLS INTO HUMAN EMBRYOS. WE DON'T ALLOW FUNDING  
4 EVEN IF THIS IS JUST BENCH RESEARCH AND THE EMBRYOS ARE  
5 NEVER USED FOR REPRODUCTIVE PURPOSES.

6 ALTA JUST POINTED OUT THERE'S AN  
7 INCONSISTENCY IN OUR APPROACH BETWEEN C AND D AND OUR  
8 REWORKED F/G. AND WE WANT TO MAKE THEM CONSISTENT OR  
9 WE THINK THERE'S A REASON FOR INCONSISTENCY.

10 WHEN I ASKED ALTA WHAT WE SHOULD WE DO, SHE  
11 SAID ASK KEVIN.

12 DR. EGGAN: THANKS, ALTA. I GUESS I'M TRYING  
13 TO FIND EXACTLY THAT LANGUAGE IN THE --

14 MS. CHARO: KEVIN, THE BOTTOM LINE IS THAT WE  
15 HAVE PROVISIONS THERE THAT TRACK THE NAS TO PROHIBIT  
16 CIRM FUNDING FOR THE MANIPULATION OF EITHER PRIMATE --  
17 OF EITHER HUMAN OR NONHUMAN PRIMATE EMBRYOS, PERIOD.  
18 NO FUNDING, PERIOD, BY INTRODUCING STEM CELLS. AND --

19 DR. EGGAN: WAIT. WAIT. WAIT. WAIT. WAIT.  
20 OKAY. BY INTRODUCING STEM CELLS. I DON'T UNDERSTAND.  
21 I CAN'T FIND THE LANGUAGE RIGHT IN FRONT OF ME.

22 MS. CHARO: KEVIN, I'M GOING TO READ IT OUT  
23 LOUD TO YOU WORD FOR WORD AND SLOWLY.

24 DR. EGGAN: IS THIS 100300?

25 MS. CHARO: YES.

1 DR. EGGAN: IS NOT ELIGIBLE FOR CIRM FUNDING,  
2 AND THERE'S B, C, D, E.

3 MS. CHARO: YES, THAT'S IT.

4 CHAIRMAN LO: SO C AND D ARE WHAT ALTA IS  
5 POINTING OUT.

6 DR. EGGAN: SO B IS THE CULTURE IN VITRO OF  
7 ANY INTACT HUMAN EMBRYO OR ANY PRODUCT OF SCNT; C IS  
8 THE INTRODUCTION OF STEM CELLS FROM A COVERED STEM CELL  
9 LINE INTO A NONHUMAN PRIMATE EMBRYO; D IS INTRODUCTION  
10 OF ANY STEM CELLS, WHETHER HUMAN OR NONHUMAN, INTO  
11 HUMAN EMBRYOS. THOSE ARE ALL FINE. E IS BREEDING ANY  
12 ANIMAL INTO WHICH STEM CELLS FROM A COVERED STEM CELL  
13 LINE HAVE BEEN INTRODUCED.

14 MS. CHARO: OKAY. STOP THERE FOR A SECOND.  
15 SO WE'VE BEEN TALKING ABOUT A SUGGESTION FROM THE  
16 PUBLIC THAT WE EXPAND THE LIST OF THINGS WE WILL NOT  
17 FUND. WE WERE CIRCLING AROUND A CONSENSUS THAT MAYBE  
18 WE WOULDN'T FUND THEM, BUT ONLY UNDER CIRCUMSTANCES  
19 THAT INVOLVE TRANSFER TO A UTERUS BECAUSE THE  
20 EXTRAUTERINE WORK MIGHT BE VALUABLE AND POSES NO RISK  
21 OF REPRODUCTIVE OUTCOMES.

22 DR. EGGAN: YES.

23 MS. CHARO: SO THEN THE QUESTION IS IF YOU  
24 TAKE A CLOSER LOOK AT C AND D ON THAT LIST, WHICH ALSO  
25 ARE ABOUT EMBRYO MANIPULATIONS, SHOULD THOSE TWO BE

1 FUNDING RESTRICTIONS THAT ARE TIED TO NO TRANSFER TO A  
2 UTERUS WHERE THE EXTRAUTERINE MANIPULATIONS ARE  
3 FUNDABLE?

4 DR. EGGAN: NOW I UNDERSTAND.

5 MS. CHARO: OR SHOULD THIS REMAIN THE WAY IT  
6 IS? THERE'S A KIND OF PUBLIC RELATIONS COMPONENT IN  
7 THIS AS MUCH AS THERE IS AN ISSUE ABOUT ACTUAL PUBLIC  
8 HEALTH AND SAFETY RISK.

9 DR. KIESSLING: WE ACTUALLY DISCUSSED BEFORE  
10 WHETHER OR NOT THERE'S SOME VALUE IN PUTTING HUMAN  
11 EMBRYONIC STEM CELL LINES INTO A MONKEY BLASTOCYST AT  
12 LEAST FOR IN VITRO CULTURE.

13 DR. EGGAN: ANN IS RIGHT. WE WENT OVER THE  
14 GROUND BEFORE EARLIER, AND I THINK WE CAME UP WITH THIS  
15 IN THE END. AND I THINK LARGELY IT WAS DUE TO THESE  
16 PUBLIC RELATION CONCERNS MORE THAN ANYTHING ELSE  
17 BECAUSE I THINK THERE'S NO -- WHETHER OR NOT JUST THE  
18 ACT OF CREATING THESE THINGS IS SOMETHING THAT WE  
19 SHOULD OR SHOULDN'T DO, YOU KNOW, AS FAR AS THE  
20 ARGUMENT ABOUT -- WELL, I WOULD LEAVE IT AT THAT.

21 AGAIN, I THINK THAT ONE COULD EASILY SEE THE  
22 UTILITY OF CREATING THESE TRANSGENIC HUMAN EMBRYOS BY  
23 SOMATIC CELL NUCLEAR TRANSPLANTATION. IT STILL IS MORE  
24 DIFFICULT TO JUSTIFY THE UTILITY OF THESE OTHER THINGS,  
25 ALTHOUGH OTHERS MAY FIND WAYS TO DO IT. SO I CAN

1 CERTAINLY SEE EXPANDING C AND D TO SAY EXACTLY AS THESE  
2 PROPOSE F AND G TO BE ONLY PROHIBITED IN THE SITUATION  
3 WHERE THAT WOULD BE TRANSFERRED TO THE UTERUS. I THINK  
4 THAT'S POSSIBLE, BUT I CAN SEE IT BOTH WAYS. I FEEL  
5 STRONGLY ABOUT THE PROTECTING THE ABILITY TO MAKE THESE  
6 TRANSGENIC HUMAN EMBRYOS FOR IN VITRO USES,  
7 PARTICULARLY IN THE DERIVATION OF NEW STEM CELL LINES.  
8 I FEEL VERY STRONGLY ABOUT THAT.

9 CHAIRMAN LO: SO, IN SUMMARY, I THINK YOU'RE  
10 SAYING THERE IS A REASON FOR HAVING AN INCONSISTENCY TO  
11 ADDRESS ALTA'S QUESTION. WE HAVE A PUBLIC COMMENT THAT  
12 I WANT TO MAKE SURE WE GET.

13 MS. GREENFIELD: YEAH. AS A REPRESENTATIVE  
14 OF THE PRO-CHOICE AND ALSO, I KNOW, THE CENTER FOR  
15 GENETICS AND SOCIETY, I THINK THE ISSUE THAT MAYBE  
16 YOU'RE MISSING A LITTLE BIT IS NOT SO MUCH THAT WE  
17 THINK THAT CIRM-FUNDED RESEARCHERS WILL USE THESE  
18 THINGS FOR REPRODUCTIVE PURPOSES, BUT THE CONCERN THAT  
19 PERHAPS SOME WAY, SOMEHOW THEY WILL GET CIRCULATED OR  
20 END UP IN THE HANDS OF PEOPLE WHO MIGHT USE THEM FOR  
21 REPRODUCTIVE PURPOSES. THAT'S IN THE PREFACE TO THE  
22 STATED REASON.

23 DR. HALL: THAT'S NOW AGAINST PROPOSITION 71,  
24 WHICH IS STATE LAW. IS THAT CORRECT?

25 DR. EGGAN: IF SOMEONE DID WHAT YOU JUST

1 SAID, THEY WOULD BE PUNISHABLE BY LAW.

2 DR. HALL: WELL, IT'S --

3 MS. CHARO: THIS IS ALTA. THAT'S EXACTLY THE  
4 DEBATE THAT'S BEEN CIRCLING AROUND THE BROWNBACK BILL.  
5 WE SHOULD CRIMINALIZE ALL CLONING RESEARCH BECAUSE IT'S  
6 NOT ENOUGH TO JUST CRIMINALIZE MISAPPROPRIATION OF USE  
7 OF EMBRYOS MADE FROM CLONING.

8 DR. HALL: WHAT SHE JUST DESCRIBED, AS I  
9 UNDERSTAND IT, IS A FORM OF REPRODUCTIVE CLONING. IF  
10 WE MAKE THESE EMBRYOS FOR USE IN THERAPEUTIC CLONING,  
11 SHE'S WORRIED THAT SOMEHOW SOMEBODY WILL GET ONE. AND  
12 IT'S NOT QUITE SPECIFIED, BUT STILL THAT SOMEBODY MIGHT  
13 GET ONE AND USE IT FOR REPRODUCTIVE CLONING, AND THAT'S  
14 ILLEGAL IN CALIFORNIA. IS THAT NOT CORRECT?

15 CHAIRMAN LO: I'M GOING TO ASK THE SPEAKER TO  
16 RESPOND.

17 MS. GREENFIELD: I'M JUST TALKING ABOUT THE  
18 NAS GUIDELINES PROHIBITS THESE, AND WE WOULD -- IN  
19 OTHER WORDS, THERE'S A DISTINCTION THERE BETWEEN THINGS  
20 THAT IF YOU INCLUDE THE WORDS FOR REPRODUCTIVE PURPOSES  
21 AND THE INCONSISTENCIES, ONE OF THE REASONS WHY THAT  
22 MIGHT NOT BE GOOD ENOUGH IS FOR THE SAME REASON THE NAS  
23 DESCRIBED THOSE THREE PROHIBITIONS. DOES THAT MAKE ANY  
24 SENSE?

25 DR. HALL: I'M SORRY. I GUESS I WOULD HAVE

1 TO LOOK IT OVER. I'M NOT QUITE SURE NOW.

2 DR. EGGAN: IT WOULD BE HELPFUL IF YOU COULD  
3 RESTATE THAT IN A DIFFERENT WAY. WHAT YOU'RE SAYING IS  
4 THAT THIS WOULD CREATE AN INCONSISTENCY WITH THE  
5 NATIONAL ACADEMY OF SCIENCE GUIDELINES, AND YOU'RE  
6 CONCERNED ABOUT THAT?

7 MS. GREENFIELD: WELL, I'M SAYING THAT THE  
8 INCONSISTENCY REVEALS THE INTENT OF ADDING THOSE TWO, F  
9 AND G. I DON'T HAVE THE NUMBERS IN FRONT OF ME. IN  
10 OTHER WORDS, IF YOU SAY YOU CAN'T DO IT FOR  
11 REPRODUCTIVE PURPOSES AND YOU DO IT FOR THE THREE  
12 ABOVE, I THINK THAT YOU'RE THEN DIMINISHING SOMEWHAT  
13 WHAT THE NAS GUIDELINES HAS SUGGESTED SHOULD BE  
14 PROHIBITED.

15 DR. HALL: I'M NOT SURE THAT'S TRUE.

16 MS. GREENFIELD: WELL, I'M NOT SURE, BUT I  
17 DON'T THINK THE NAS STANDARDS SAY FOR REPRODUCTIVE  
18 PURPOSES.

19 DR. HALL: REPRODUCTIVE PURPOSES, SO LET'S  
20 SAY WE MAKE A BLASTOCYST BY SCNT AND THAT INVOLVES A  
21 GENETIC MANIPULATION. AND WHAT WE'RE TALKING ABOUT, AS  
22 I UNDERSTAND IT, IS TO THEN TAKE THE INNER CELL MASS,  
23 MAKE STEM CELLS THAT CONTAIN THAT GENETIC MANIPULATION.  
24 THOSE CANNOT BE USED TO MAKE A HUMAN BEING, STEM CELLS  
25 CANNOT BE.

1 AS I UNDERSTAND, THEN THE CONCERN IS THAT  
2 SAME BLASTOCYST MIGHT BE THEN IMPLANTED IN THE UTERUS  
3 AND GIVE RISE TO A HUMAN BEING, A CHILD.

4 MS. GREENFIELD: I'M JUST POINTING OUT THE  
5 POSSIBLE INTENT OF DRAWING A LINE BETWEEN DOING IT AT  
6 ALL AND DOING IT, BUT NOT DOING IT FOR REPRODUCTIVE  
7 PURPOSES. I'M JUST DRAWING -- I'M JUST SAYING THAT  
8 THAT'S POTENTIALLY THE SAME INTENT FOR THE THINGS WE  
9 SUGGEST.

10 DR. HALL: ARE YOU CONCERNED THAT IF ONE  
11 MAKES THOSE, IF PERMITTED TO MAKE THOSE EMBRYOS USED TO  
12 MAKE STEM CELL LINES WILL INCREASE THE PROBABILITY THAT  
13 THEY EMBRYOS WILL BE USED ILLEGALLY FOR REPRODUCTIVE  
14 PURPOSES? IS THAT FAIR OR IS THAT NOT WHAT YOU'RE  
15 SAYING? I'M TRYING TO UNDERSTAND.

16 MS. CHARO: ZACH, IF I MIGHT, I'M NOT SURE  
17 THAT THE DEBATE THAT IS SHAPING UP ON THIS IN THIS  
18 DIALOGUE IS THE ONE THAT IS ACTUALLY ON POINT FOR THE  
19 TEXT THAT WE'RE DISCUSSING HERE. IT'S RELATED, BUT I'M  
20 NOT SURE IT'S EXACTLY ON POINT. THE NATIONAL ACADEMY'S  
21 GUIDELINES, WHICH WERE THE STARTING POINT FOR THIS  
22 COMMITTEE'S WORK, DO STATE WITHOUT ANY RESERVATIONS  
23 THAT ONE OUGHT NOT PLACE A HUMAN EMBRYONIC STEM CELL  
24 INTO A PRIMATE EMBRYO, AND THAT ONE AUGHT NOT PLACE ANY  
25 KIND OF STEM CELL INTO A HUMAN EMBRYO. AND IT DOESN'T



1 SAY DON'T DO IT WHEN YOU THINK YOU MIGHT USE THE EMBRYO  
2 FOR REPRODUCTION, DON'T DO IT WHEN YOU'RE GOING TO  
3 TRANSFER INTO A UTERUS. IT JUST SAYS DON'T DO IT.

4 IN A SENSE WHAT I WAS ASKING HERE WAS WHETHER  
5 OR NOT WE WANTED TO THINK THAT THROUGH AFRESH ABOUT  
6 WHETHER OR NOT SUCH A PROHIBITION SHOULD APPLY ONLY  
7 WHERE THE RESULTING PRIMATE EMBRYO OR HUMAN EMBRYO, NOW  
8 BEEN MANIPULATED, WAS GOING TO BE PLACED INTO A UTERUS.  
9 THE REASON I WAS ASKING THAT QUESTION IS THAT WE WERE  
10 LOOKING AT THE NO TRANSFER INTO A UTERUS DEMARCATION  
11 LINE AS A VALUABLE ONE IN ADDRESSING OTHER FORMS OF  
12 GENETIC MANIPULATION OTHER THAN A STEM CELL TRANSPLANT  
13 INTO AN EMBRYO.

14 NOW, AT THE TIME THE NAS GUIDELINES WERE  
15 WRITTEN, THE SAME DEBATE TOOK PLACE, AND ONE OF THE  
16 RESPONSES AT THE TIME WAS, WELL, THERE'S NO SCIENTIFIC  
17 NEED THAT CAN BE IDENTIFIED FOR DOING RESEARCH THAT  
18 INVOLVES TAKING A HUMAN EMBRYONIC STEM CELL AND PUTTING  
19 IT INTO A PRIMATE EMBRYO. THERE'S NO SCIENTIFIC NEED  
20 WE CAN IDENTIFY FOR PUTTING ANY EMBRYONIC STEM CELLS  
21 INTO HUMAN EMBRYOS. SO LET'S JUST WRITE SOMETHING  
22 THAT'S REALLY CLEAR.

23 AND WHAT WE HEARD JUST A MOMENT AGO, I THINK,  
24 IS THAT THAT IS STILL THE CASE, THAT THERE'S NO  
25 SCIENTIFIC NEED TO DO SUCH PREIMPLANTATION RESEARCH,

1 BUT IN THE CASE OF OTHER KINDS OF GENETIC  
2 MANIPULATIONS, LIKE THE ONES THAT KEVIN WAS TALKING  
3 ABOUT, THERE IS SUCH A NEED, WHICH MEANS WE ABSOLUTELY  
4 HAVE TO FOCUS ON WHETHER OR NOT WE WANT TO NOT FUND  
5 THAT RESEARCH OR FUND IT WITH A CONDITION THAT YOU  
6 CAN'T TRANSFER TO A UTERUS AND LEAVE SOME DEGREE OF  
7 CONSISTENCY BETWEEN THE PROVISIONS WHICH WILL ALWAYS BE  
8 REVISITABLE IN THE FUTURE. RIGHT. WE COULD MAKE THEM  
9 ALL CONSISTENT. WE COULD TIE EVERYTHING TO DON'T  
10 TRANSFER INTO A UTERUS, AND THE REAL DOWNSIDE WOULD BE  
11 MORE PUBLIC RELATIONS THAN ANYTHING ELSE.

12 I THINK THE DIALOGUE BEGAN WITH THE ASSERTION  
13 THAT IF THINGS ARE DONE IN THE LABORATORY, IT INCREASES  
14 THE RISK OF MISAPPROPRIATION AND MISUSE THAT WILL LEAD  
15 TO ACTIONS THAT VIOLATE THE EXISTING STATE LAW. AND  
16 THE ANSWER, YEAH, THAT'S A RISK YOU RUN WITH  
17 EVERYTHING, BUT YOU CAN'T OUTLAW THE WORLD BECAUSE  
18 SOMEBODY IS GOING TO BREAK THE LAW. WE HAVE, AS YOU  
19 POINTED OUT, STATE LAW THAT CRIMINALIZES THE VERY  
20 ACTIONS THAT PEOPLE ARE SAYING THEY FEAR. SO IT'S  
21 REALLY MORE STYLISTIC CHOICE AND POLITICAL CHOICE  
22 BEFORE US.

23 DR. PETERS: ALTA, I THINK YOU'RE KEEPING US  
24 RIGHT ON THE POINT AND YOU ARE DOING IT VERY WELL. I  
25 WAS ACTUALLY UNHAPPY WITH THE NAS GUIDELINES WHEN IT

1 FIRST CAME OUT ON THIS POINT. I EVEN SAID SO A COUPLE  
2 OF TIMES. AND THESE POTENTIAL, ALTHOUGH NOT MAYBE  
3 ACTUAL, BUT POTENTIAL RESTRICTIONS ON SCIENTIFIC  
4 RESEARCH WITH REGARD TO EMBRYOS THAT WILL NOT BE  
5 IMPLANTED SEEM TO BE UNNECESSARY. AND I DON'T REALLY  
6 KNOW WHAT ETHICAL FOUNDATION THERE WOULD BE FOR THOSE  
7 PROSCRIPTIONS OTHER THAN PUBLIC RELATIONS.

8 SO I THINK, IF I HEARD YOU CORRECTLY, A  
9 POLICY ON WHAT ARE THE THINGS FOR REPRODUCTION THAT WE  
10 WILL NOT FUND, WE'LL PUT THESE THINGS IN THAT CATEGORY,  
11 BUT THAT DOESN'T MEAN THAT IN VITRO THESE KINDS OF  
12 EXPERIMENTS COULDN'T GO AHEAD SHOULD THE RESEARCHER  
13 DEEM THEM APPROPRIATE.

14 CHAIRMAN LO: I'M TRYING TO SORT OUT WHAT --

15 DR. HALL: BERNIE, I'M SORRY. WE'RE GONG TO  
16 HAVE TO SIGN OFF HERE. BOTH KEVIN AND I ARE DUE AT  
17 ANOTHER MEETING SOME WAY FROM HERE IN ABOUT 15 MINUTES.  
18 IF THERE'S ANY LAST WORD OR HELP, WE'LL BE HAPPY TO DO  
19 IT.

20 CHAIRMAN LO: NO. WE'RE NOT QUITE THAT CLOSE  
21 YET. THANKS. WE MAY NEED TO COME BACK TO THIS.

22 DR. HALL: GOOD LUCK AND THANKS FOR A GOOD  
23 MEETING.

24 CHAIRMAN LO: THANKS VERY MUCH FOR JOINING  
25 US. LET'S GO BACK. WE HAD A PROPOSAL FROM THE PUBLIC

1 TO ADD TO THE LIST OF THINGS THAT WERE NOT ELIGIBLE FOR  
2 FUNDING. THESE INVOLVE SOME SORT OF GENETIC  
3 MANIPULATION. WE THOUGHT ABOUT THAT, AND KEVIN RAISED  
4 SOME POSSIBILITIES OF RESEARCH THAT MIGHT BE  
5 SCIENTIFICALLY USEFUL IF IT WERE DONE IN VITRO AND  
6 WANTED TO PRESERVE THE ABILITY FOR CIRM TO FUND THAT  
7 KIND OF RESEARCH WHICH IS DIFFERENT THAN WHAT'S IN C  
8 AND D. SO HE'S PARTICULARLY TALKING ABOUT GENETICALLY  
9 MANIPULATING A NUCLEUS WHICH WOULD BE INTRODUCED INTO  
10 AN OOCYTE USING SCNT TO FORM A STEM CELL LINE. AND  
11 NONE OF THAT COULD BE USED, OF COURSE, FOR REPRODUCTION  
12 UNDER BOTH OUR REGULATIONS AND PROPOSITION 71 AND  
13 EXISTING CALIFORNIA LAW.

14 SO IT SEEMS LIKE RIGHT NOW THERE'S NO NEED TO  
15 SAY WE'RE NOT GOING TO FUND IT BECAUSE IT'S ILLEGAL.  
16 WE'RE NOT GOING TO FUND IT.

17 THERE ARE OTHER THINGS THAT WERE SUGGESTED IN  
18 F AND G BY THE COMMENTERS, THAT WE ALSO NOT FUND, AND I  
19 GUESS THE QUESTION IS DO WE WANT TO INCLUDE THAT AS NOT  
20 FUNDABLE OR NOT. AND IT HAS NOW BROUGHT UP THE  
21 QUESTION OF, WELL, YOU SEEM TO BE SAYING AROUND THE  
22 ISSUE THAT IT'S NOT THE ACTION ITSELF, BUT IT'S USE OF  
23 THE PRODUCTS OF THAT RESEARCH FOR REPRODUCTIVE PURPOSES  
24 THAT WAS OBJECTIONABLE, AND THEN SHE POINTED OUT IS  
25 INCONSISTENT WITH WHAT WE HAD IN C AND D.

1                   SOUNDS LIKE I THINK WE NEED TO SEPARATE OUT  
2   WHAT WE WANT TO DO WITH C AND D AND WHAT WE WANT TO DO,  
3   IF AT ALL, TO INSERT A NEW F/G.  THE WAY I READ IT, WE  
4   DON'T NEED TO SAY ANYTHING ABOUT A MANIPULATION OF A  
5   NUCLEUS THAT WILL BE INTRODUCED INTO A HUMAN OOCYTE  
6   BECAUSE THE REPRODUCTIVE USES ARE BANNED, AND WE VERY  
7   DEFINITELY, AS KEVIN ARGUED, WANT TO ALLOW THAT FOR  
8   RESEARCH, AND ACTUALLY A HIGH PRIORITY FOR CIRM  
9   FUNDING.

10                   AND IT SEEMS TO ME ALSO THAT ARTIFICIAL  
11  CHROMOSOME, I'M NOT SURE WHAT THAT MEANS, BUT YOU  
12  COULD, FOR INSTANCE, IMAGINE SOMEONE WANTING, AGAIN FOR  
13  RESEARCH PURPOSES, TO CREATE A STEM CELL LINE THAT  
14  MIGHT BE USED FOR THERAPY, NOT FOR REPRODUCTIVE  
15  PURPOSES, INTRODUCING A GENE, NOT A WHOLE CHROMOSOME,  
16  BUT A GENE INTO A HUMAN -- A MANIPULATED GENE TO A  
17  HUMAN OOCYTE.

18                   I GUESS I'M WONDERING OUT OF THE SUGGESTED F  
19  AND G WHAT IS IT THAT WE WANT TO ADD TO OUR LIST OF NOT  
20  ELIGIBLE FOR CIRM FUNDING IF IT'S USED FOR REPRODUCTIVE  
21  PURPOSES OR, AS WAS FURTHER SUGGESTED, WHETHER OR NOT  
22  IT'S USED FOR REPRODUCTIVE PURPOSES, WE WANT TO NOT  
23  FUND IT BECAUSE IT MAY BE MISUSED FOR REPRODUCTIVE  
24  PURPOSES BY SOMEBODY ELSE.

25                   I DON'T KNOW IF THAT'S A FAIR STATEMENT.  I'M

1 NOT SURE WHAT WE'RE LEFT WITH IN TERMS OF THINGS WE  
2 WOULD DEFINITELY NOT WANT TO FUND UNDER CIRM THAT  
3 INVOLVES SOME SORT OF GENETIC MANIPULATION, WHICH IS TO  
4 ME DIFFERENT THAN INTRODUCING STEM CELLS INTO EMBRYOS.

5 DR. TAYLOR: BERNIE, I HATE TO MAKE IT MORE  
6 COMPLICATED, BUT I GUESS IF YOU ARE GOING TO FOLLOW  
7 THAT LINE OF THINKING, AND BASED ON WHAT KEVIN  
8 MENTIONED ACTUALLY IN SORT OF SIGNING OFF, I COULD  
9 IMAGINE POTENTIALLY THAT THERE COULD BE ADVANTAGES OF  
10 INTRODUCING STEM CELLS INTO A HUMAN BLASTOCYST IN VITRO  
11 IN TERMS OF DIFFERENTIATING OR POTENTIALLY MANIPULATING  
12 THAT STEM CELL AGAIN WITH NO INTENT TO TRANSFER THAT  
13 EVER BACK INTO A UTERUS OR TO USE THAT AS A MECHANISM  
14 TO CONDITION THE CELL POTENTIALLY IN SOME WAY TO MAYBE  
15 DIFFERENTIATE ALONG A PATHWAY THAT MIGHT BE  
16 THERAPEUTICALLY BENEFICIAL.

17 SO THERE'S ETHICAL AND, I SUSPECT, IF THESE  
18 GUIDELINES CAME FROM THE NAS WITH CONCERN THAT ANY KIND  
19 OF MANIPULATION OF A LIVING HUMAN EMBRYO WAS  
20 POTENTIALLY CROSSING THE LINE, THAT LINE IS STARTING TO  
21 FADE FOR ME A LITTLE BIT. I DON'T REALLY QUITE SEE  
22 HOW, IF WE ARE CONSIDERING APPROVING SOME GENETIC  
23 MANIPULATION OF AN EMBRYO IN VITRO FOR THERAPEUTIC  
24 PURPOSES, THAT ONE WOULD NECESSARILY PRECLUDE THE  
25 INTRODUCTION OF A STEM CELL INTO A HUMAN EMBRYO FOR THE

1 SAME KINDS OF PURPOSES.

2 MR. TOCHER: IF I COULD JUST REVIEW THE  
3 DEFINITION FROM PROP 71, HUMAN REPRODUCTIVE CLONING.  
4 I'M NOT SURE HOW IT MAY AFFECT THINGS, BUT AT LEAST THE  
5 WAY IT DEFINES, WHICH IS THE SUBJECT OF CONSTITUTIONAL  
6 PROHIBITION ON THE INSTITUTE FROM FUNDING, THE  
7 CONSTITUTION SAYS, "NO FUNDS AUTHORIZED OR MADE  
8 AVAILABLE TO THE INSTITUTE SHALL BE USED FOR RESEARCH  
9 INVOLVING HUMAN REPRODUCTIVE CLONING." SO THE  
10 DEFINITION OF HUMAN REPRODUCTIVE CLONING MEANS THE  
11 PRACTICE OF CREATING OR ATTEMPTING TO CREATE A HUMAN  
12 BEING BY TRANSFERRING THE NUCLEUS FROM A HUMAN CELL  
13 INTO AN EGG CELL FROM WHICH THE NUCLEUS HAS BEEN  
14 REMOVED FOR THE PURPOSE OF IMPLANTING A RESULTING  
15 PRODUCT IN THE UTERUS TO INITIATE A PREGNANCY.

16 IT SEEMS AS THOUGH SOME OF THE DISCUSSION  
17 ABOUT SOME OF THESE PROVISIONS IS GOING BEYOND THAT, AT  
18 LEAST FROM THE MINIMAL SCIENCE THAT I CAN UNDERSTAND.  
19 SO I JUST WANTED TO KEEP UP THERE WHAT THE PROHIBITION  
20 IN THE ACT IS.

21 MS. CHARO: I APPRECIATE THAT, SCOTT.  
22 OBVIOUSLY YOU APPRECIATE THAT WHAT YOU'RE TALKING ABOUT  
23 NOW IS LOOKING AT PARALLELS BECAUSE IT'S NOT ON POINT  
24 FOR THIS. I THINK ROB HAS PUT HIS FINGER ON IT, WHICH  
25 IS THAT AS A MATTER OF LOGIC, IF THE EMBRYO IS NOT TO

1 BE CONSIDERED THE KIND OF ENTITY THAT CAN BE HARMED BY  
2 BEING DESTROYED, WHICH IS WHAT IS ROUTINELY GOING TO BE  
3 DONE FOR SURPLUS EMBRYOS THAT ARE USED TO GENERATE STEM  
4 CELL LINES, THEN IT MAKES LITTLE SENSE TO CONSIDER IT  
5 TO BE HARMED BY BEING MANIPULATED BEFORE IT IS  
6 DESTROYED. AND UNDER THAT THEORY, COLD AND CALLOUS AS  
7 IT SOUNDS, RIGHT, IT WOULD SEEM LOGICALLY THAT ONE  
8 COULD MANIPULATE IN ANY FASHION AND THAT THE ONLY REAL  
9 CONCERN IS THAT YOU MAKE SURE THAT IN THE END THAT  
10 EMBRYO IS NOT TRANSFERRED TO A UTERUS, WHETHER IT IS  
11 THE RESULT OF CLONING OR SOME OTHER MANIPULATION  
12 BECAUSE YOUR REAL CONCERN IS IN A NEWBORN CHILD DOWN  
13 THE ROAD NINE MONTHS LATER WHO COULD SUFFER HARM.

14 DR. TAYLOR: IN LESS THAN 12 DAYS.

15 MS. CHARO: AND WE'VE GOT ANOTHER PROVISION  
16 HERE THAT ABSOLUTELY SAYS WE CAN'T CULTURE BEYOND 12  
17 DAYS. SO WE KNOW THAT WE'RE TALKING ABOUT A 12-DAY  
18 WINDOW FOR THE MANIPULATIONS.

19 AS A MATTER OF KIND OF POLITICAL REALITY, IF  
20 THERE'S NO SCIENTIFIC NEED TO DO SUCH MANIPULATIONS,  
21 AND IF THERE IS THE SENSE THAT THE MANIPULATIONS WOULD  
22 GENERATE CONCERN AND OPPOSITION AND MISUNDERSTANDING,  
23 ONE MIGHT SAY WE WILL NOT FUND -- WE WILL WRITE  
24 GUIDELINES THAT CLARIFY THAT WE'RE NOT FUNDING THIS  
25 BECAUSE, IN FACT, SCIENTIFICALLY WE HAVE NO NEED OR



1 INTENT TO FUND IT. THE ONLY REASON I'M STUMBLING HERE  
2 IS THE POLITICAL ISSUE, I THINK, IS CLEAR, BUT  
3 REGULATIONS HAVE A LIFE THAT SEEMS TO GO ON AND ON AND  
4 ON EVEN AFTER THE FACTS HAVE CHANGED. SO I'M CONCERNED  
5 WITH THE ISSUE OF HOW ONE WOULD CHANGE THE REGULATIONS  
6 IF THE EQUATION ALTERED AND WE DISCOVERED THAT THERE  
7 REALLY WAS SOME DRIVING NEED TO DO WORK.

8 DR. PETERS: ALTA, I THINK, AGAIN, YOU  
9 FORMULATE THE ISSUE VERY CLEARLY AND CONSCIENTIOUSLY  
10 WRESTLED IT, BUT I'M SO PERSUADED BY THE LOGIC OF YOUR  
11 FIRST ARGUMENT, THAT I REALLY DON'T THINK WE NEED TO  
12 CAPITULATE TO WHAT WE FEAR MIGHT BE THE PUBLIC REACTION  
13 WITH REGARD TO THE SECOND COMPROMISE BECAUSE I MEAN AT  
14 BEST IT IS VAGUE. WE CERTAINLY HAVE A VERY  
15 CONSERVATIVE WINDOW, THE 12-DAY WINDOW, WITHIN WHICH WE  
16 CAN WORK ON THE EMBRYO BEFORE ITS DESTRUCTION.

17 SO THEN TO -- LET ME JUST KIND OF DRAW OUT  
18 THE IMPLICATIONS OF THE SECOND OF YOUR TWO  
19 ALTERNATIVES. WE WOULD CONSTRICT, LIMIT THE SCOPE OF  
20 SCIENTIFIC RESEARCH ON THE BASIS OF A PERCEIVED  
21 SPECULATIVE NEGATIVE PUBLIC REACTION. AND I'M JUST  
22 SAYING I DON'T FIND THAT SUFFICIENT REASON FOR PUTTING  
23 THAT INTO A REGULATION, AS YOU SUGGESTED MIGHT LAST TEN  
24 YEARS OR SOMETHING.

25 MS. CHARO: JUST A FRIENDLY CLARIFICATION.

1 WE'RE NOT TALKING ABOUT PROHIBITING ANYTHING. WE'RE  
2 TALKING ABOUT WHAT WE WOULD CHOOSE OR NOT CHOOSE TO  
3 FUND AS A DISCRETIONARY MATTER, WHICH IS A SLIGHTLY  
4 DIFFERENT KIND OF ANALYSIS, RIGHT.

5 DR. PETERS: YES, IT IS. BUT STILL, ALTA,  
6 I'D LIKE TO HAVE YOU SPEAK TO MY ARGUMENT ABOUT THE  
7 INTERNAL LOGIC OF MAKING THIS KIND OF A DECISION, THAT  
8 WE'RE NOT GOING TO FUND A CERTAIN AREA OF SCIENCE WHICH  
9 ON RELATED ISSUES WE THINK IS LEGITIMATE, AND IN THIS  
10 CASE WE'RE NOT GOING TO FUND IT BECAUSE OF SOME SORT OF  
11 VAGUE PERCEPTION ABOUT A NEGATIVE PUBLIC REACTION. I  
12 JUST WONDER IF THAT'S SUFFICIENT GROUNDS. WHAT IF -- I  
13 DON'T WANT TO PUSH IT THIS FAR, BUT WHAT IF IT WERE  
14 SORT OF A PRECEDENT THAT WE WOULDN'T FUND CERTAIN AREAS  
15 OF SCIENCE JUST IN GENERAL BECAUSE WE'RE CONCERNED  
16 ABOUT THE POLITICAL IMPORT WHEN YOU SORT OF MADE OTHER  
17 DECISIONS THAT WOULD PERMIT THIS KIND OF OR ENCOURAGE  
18 THIS KIND OF RESEARCH ON A DIFFERENT BASIS.

19 SO IT'S A CONSISTENCY ARGUMENT. IN OTHER  
20 WORDS, WHY ARE YOU NOT PERSUADED TOTALLY AND COMPLETELY  
21 BY THE LOGIC OF THE FIRST SIDE OF THE HORN OF THE  
22 DILEMMA THAT YOU PUT US ON?

23 MS. CHARO: BECAUSE I ACTUALLY BELIEVE THAT  
24 IN CASES OF DISCRETIONARY DECISIONS ABOUT FUNDING, THE  
25 VIEWS OF THE PUBLIC HAVE SOME LEGITIMATE WEIGHT IN THE

1 DISCUSSION. AND THAT IF YOU HAVE PEOPLE WHO ARE DEEPLY  
2 PERTURBED BY SOMETHING, AND YOU HAVE NO OFFSETTING NEED  
3 TO DO IT, THAT MAY BE AN ARGUMENT FOR WHY YOU WOULD  
4 CHOOSE NOT TO FUND IT, AND YOU WILL CONTINUE TO  
5 MAINTAIN THAT CHOICE UNLESS AND UNTIL THE DAY COMES  
6 THAT THERE IS A SUFFICIENT NEED FOR IT THAT YOU NOW  
7 HAVE TO REVISIT THE PUBLIC DISQUIET VERSUS THE  
8 POTENTIAL BENEFITS TO INDIVIDUALS NOW AND IN THE FUTURE  
9 AND THE BALANCE OF INTERESTS MIGHT CHANGE.

10 I GUESS IT'S BECAUSE I TAKE THE PUBLIC  
11 CONCERN SERIOUSLY AS AN ELEMENT OF THE ETHICAL ANALYSIS  
12 IN AND OF ITSELF AND NOT JUST THE CONCERN ABOUT THE  
13 STATUS OF THE EMBRYO.

14 DR. PETERS: COULD I ASK ABOUT THE -- DO YOU  
15 HAVE SUFFICIENT CLARITY THAT THIS IS NOT A NEED THAT  
16 OUR SCIENTISTS HAVE? WE'VE GOT SOME SCIENTISTS IN THE  
17 ROOM. I MEAN IF THERE IS ABSOLUTELY NO NEED, THEN IT  
18 PROBABLY DOESN'T MAKE ANY DIFFERENCE, BUT IT JUST SEEMS  
19 TO ME THAT TO CLOSE THE DOOR IN ADVANCE, OF COURSE, YOU  
20 SAY WE COULD REOPEN IT, BUT I GUESS I'M NOT THAT  
21 CONVINCED THAT THERE COULDN'T BE A REASONABLE NEED FOR  
22 THE SCIENTISTS IN THE FUTURE TO DO THAT.

23 CHAIRMAN LO: TED, LET ME JUST SAY THIS WAS  
24 VERY EXTENSIVELY DISCUSSED BY ALL THE INSTITUTIONS WHO  
25 HAVE APPLIED FOR FUNDING UNDER THE TRAINING GRANTS, ALL

1 THE UC CAMPUSES, SCRIPPS, BURNHAM, STANFORD, USC. AND  
2 A LOT OF THE PEOPLE WERE SCIENTISTS, AND NONE OF THEM  
3 RAISED AN OBJECTION TO C AND D TO SAY THIS IS NOT  
4 ALLOWING US TO DO IMPORTANT RESEARCH THAT WE'RE READY  
5 TO DO AT THIS TIME. I GUESS I WOULD --

6 DR. PETERS: THANKS. THAT'S QUITE RELEVANT.

7 CHAIRMAN LO: AGAIN, I THINK YOU'RE RIGHT,  
8 THAT YOU DON'T WANT TO SORT OF BALANCE SPECULATIVE  
9 HARMS VERSUS KNOWN SCIENTIFIC BENEFITS. BUT AT THIS  
10 POINT THE SCIENTIFIC WARRANT FOR DOING C AND D IS ALSO  
11 SPECULATIVE. I THINK WE'D BE, AGAIN, TO USE SHERRY'S  
12 LANGUAGE FROM THIS MORNING, MORE CONSERVATIVE TO SAY  
13 WHEN THE TIME COMES WHEN SCIENTISTS SAY WE'RE NOW  
14 STARTING TO THINK ABOUT EXPERIMENTS THAT DON'T FIT  
15 UNDER C AND D, BUT WOULD BE REALLY USEFUL, THEN THAT'S  
16 THE TIME TO REVISIT. OTHERWISE TO SORT OF GO BACK ON  
17 WHAT WE HAVE PREVIOUSLY SAID WITHOUT A COMPELLING  
18 ARGUMENT AT THIS TIME, IT'S NOT SOMETHING WE NEED TO DO  
19 RIGHT NOW AND WE CAN WAIT TILL IT COMES UP.

20 DR. KIESSLING: HOW DOES THAT RELATE TO F AND  
21 G?

22 MS. CHARO: F AND G NOW WE HAVE ACTUAL  
23 SCIENTIFIC NEED TO DO IT.

24 CHAIRMAN LO: I THINK WE WANT TO SAY F AND  
25 G -- MY SENSE IS, I DON'T KNOW HOW TO WORD THIS, BUT F

1 AND G WE WOULD LIKE TO BE ABLE TO FUND SCIENTIFIC  
2 NONREPRODUCTIVE PURPOSES, BUT IT'S NOW ALREADY  
3 FORBIDDEN AND SOME OF THIS ALREADY IS WITHIN PROP 71.  
4 WE DON'T WANT THESE KINDS OF TECHNIQUES USED FOR  
5 REPRODUCTION BY CIRM-FUNDED RESEARCHERS.

6 THE OTHER QUESTION RAISED BY THE PUBLIC WAS  
7 WHAT ABOUT THE TECHNOLOGY BEING USED BY SOMEONE WHO'S  
8 NOT A CIRM-FUNDED RESEARCHER SINCE YOU'RE MAKING THIS  
9 INFORMATION WIDELY AVAILABLE ABOUT HOW TO DO IT. I  
10 GUESS THAT'S A SEPARATE ISSUE. AT LEAST ON THE CIRM  
11 FUNDING, DO WE WANT TO -- RIGHT NOW WE DON'T SAY  
12 ANYTHING ABOUT THIS GENETIC MANIPULATION INVOLVING AN  
13 EMBRYO. SO KEVIN'S PROJECT COULD GET FUNDED. NO ONE  
14 COULD DO IT UNDER CIRM FUNDING FOR REPRODUCTIVE  
15 PURPOSES, BUT F AND G ACTUALLY PROPOSE TO BAN OTHER  
16 TYPES OF GENETIC MANIPULATION. AND I THINK THE SENSE  
17 OF OUR COMMITTEE WAS THESE TYPES OF GENETIC  
18 MANIPULATION WOULD ONLY BAN, IF AT ALL, IF IT WAS USED  
19 FOR REPRODUCTIVE PURPOSES. I GUESS I'M NOT HEARING A  
20 CLEAR MESSAGE FROM THE COMMITTEE THAT WE WANT TO BAN IT  
21 AT ALL AT THIS POINT, WHICH IS WHAT OUR CURRENT  
22 REGULATIONS DON'T ADDRESS.

23 MS. CHARO: I THOUGHT I HEARD THAT WE WERE  
24 GOING TO BAN THE TRANSFER TO A UTERUS OR THE  
25 GENETICALLY MODIFIED HUMAN EMBRYO.

1                   CHAIRMAN LO:  SO THAT STRIKES ME AS WHEN YOU  
2 TAKE F AND G AND SORT OF TAKE OUT WHAT'S ALREADY BANNED  
3 BECAUSE REPRODUCTIVE CLONING IS BANNED, WHAT'S LEFT IS  
4 THE RESEARCH THAT TAKES AN EMBRYO AND GENETICALLY  
5 ALTERS IT AND THEN PUTS IN... AND TO SAY THAT WE'RE NOT  
6 GOING TO FUND THAT FOR SURE, BUT LEAVE WE'RE OPEN TO  
7 FUNDING IF IT'S JUST FOR RESEARCH LAB PURPOSES ONLY.

8                   MR. LOMAX:  SO THIS WOULD ENCAPSULATE THE  
9 SPIRIT OF, HOPEFULLY, BOTH F AND G, AND THE STATEMENT  
10 WOULD READ, "TRANSFER TO A UTERUS OF A HUMAN EMBRYO  
11 THAT HAS BEEN GENETICALLY MODIFIED."

12                   CHAIRMAN LO:  SO WE COULD USE CIRM FUNDING.  
13 SO THAT'S AN EXTRA PROHIBITION ON CERTAIN TYPES OF  
14 RESEARCH.

15                   MR. TOCHER:  GEOFF, CAN YOU DO THAT ONE MORE  
16 TIME?

17                   MR. LOMAX:  TRANSFER TO A UTERUS OF A  
18 HUMAN -- LET ME START OVER AGAIN.  LET ME JUST READ  
19 THIS ONCE MORE.

20                   TRANSFER TO THE UTERUS OF A HUMAN EMBRYO --

21                   MS. CHARO:  NO.  TRANSFER TO A UTERUS OF A  
22 HUMAN EMBRYO THAT HAS BEEN GENETICALLY MODIFIED.

23                   CHAIRMAN LO:  SO YOU DON'T WANT TO TRANSFER A  
24 HUMAN EMBRYO THAT HAS BEEN GENETICALLY MODIFIED.  YOU  
25 CAN'T PUT THAT IN A UTERUS.

1 MS. CHARO: ACTUALLY WE CAN SIMPLIFY IT AND  
2 JUST SAY TRANSFER TO A UTERUS OF A GENETICALLY MODIFIED  
3 HUMAN EMBRYO. HOW ABOUT THAT? THAT MAKE IT EASIER TO  
4 UNDERSTAND?

5 CHAIRMAN LO: PUBLIC COMMENT PARTICULARLY  
6 FROM THE PEOPLE WHO MADE THE ORIGINAL SUGGESTION?

7 DR. KIESSLING: JUST FOR THE RECORD, I CAN'T  
8 FIND ANY EVIDENCE FOR G IN THE NATIONAL ACADEMY  
9 GUIDELINES. MAYBE SOMEBODY WHO'S MORE FAMILIAR WITH  
10 THOSE GUIDELINES. I DON'T SEE ANYTHING IN THE NATIONAL  
11 ACADEMY GUIDELINES ABOUT GENETIC ALTERATION OF A HUMAN  
12 EMBRYO.

13 MS. CHARO: G WAS NOT FROM THE GUIDELINES. G  
14 WAS FROM THE PUBLIC COMMENTERS.

15 DR. KIESSLING: RIGHT, BUT I THOUGHT THE  
16 PUBLIC COMMENT TOLD THEM -- THAT IT WAS BASED ON, THAT  
17 IT WOULD MAKE IT MORE CONSISTENT WITH THE NAS  
18 GUIDELINES.

19 MS. CHARO: NO. NO. THAT DIALOGUE HAD TO DO  
20 WITH WHETHER WE MODIFY THE EXISTING C AND D KIND OF  
21 GLOBAL PROHIBITIONS ON STEM CELL INTRODUCTION INTO  
22 EMBRYOS TO APPLY ONLY WHERE IT'S TRANSFERRED TO A  
23 UTERUS AND WHERE THE NAS GUIDELINES MADE NO SUCH  
24 CONSTRAINT ON THE PROHIBITION. AT LEAST THAT'S HOW I  
25 UNDERSTOOD THE CONVERSATION.

1                   CHAIRMAN LO: ALL RIGHT. ANY FURTHER  
2 DISCUSSION OF THIS PROPOSED ADDITION TO OUR  
3 REGULATIONS? INVITING MEMBERS OF THE PUBLIC.

4                   DR. PETERS: LET ME JUST BE CLEAR ON WHAT  
5 WE'RE VOTING ON. WE ARE GOING TO ADD THIS PARTICULAR  
6 PROVISION, AND WE'RE NOT GOING TO CHANGE THE EXISTING  
7 WORDING; IS THAT CORRECT?

8                   CHAIRMAN LO: OF C AND D. GEOFF, ONE MORE  
9 TIME.

10                  MR. LOMAX: TRANSFER TO A UTERUS OF  
11 GENETICALLY MODIFIED HUMAN EMBRYO.

12                  CHAIRMAN LO: THIS FITS UNDER THE FOLLOWING  
13 ACTIVITIES ARE NOT ELIGIBLE FOR CIRM FUNDING, AND WE  
14 ADD IN UNDER HERE --

15                  MS. LANSING: SAY THAT SENTENCE AGAIN.

16                  MR. LOMAX: TRANSFER TO A UTERUS OF  
17 GENETICALLY MODIFIED HUMAN EMBRYO.

18                  CHAIRMAN LO: SO WE'RE ALLOWING IT FOR  
19 RESEARCH PURPOSES IN THE LAB, BUT YOU CAN'T --

20                  MS. LANSING: WE'RE MAKING IT STRICTER.

21                  CHAIRMAN LO: WE'RE ADDING THAT TO ADDRESS  
22 THE CONCERNS ABOUT TRANSMITTING GENETIC MODIFICATIONS  
23 TO THE NEXT GENERATION. SOMEONE WANTS TO MOVE THAT WE  
24 ADOPT --

25                  DR. PETERS: SO MOVED.



1 MS. CHARO: SECOND.

2 CHAIRMAN LO: AGAIN, LAST CALL FOR  
3 DISCUSSION. OKAY. ALL THOSE IN FAVOR. AND AGAIN, NOW  
4 IT'S JUST A SENSE OF THE COMMITTEE BECAUSE I HAVE  
5 NOBODY ON THE TELEPHONE AS FAR AS I KNOW. ALL THOSE IN  
6 FAVOR. ANY OPPOSED? ANY ABSTENTION? IF SOMEONE COULD  
7 JUST RECORD THE NUMBER OF PEOPLE HERE.

8 MR. TOCHER: EIGHT.

9 CHAIRMAN LO: NOW I WOULD LIKE TO RETURN,  
10 HAVING HAD A FULL LUNCH AND ADEQUATE TIME TO DIGEST,  
11 I'D LIKE TO RETURN TO WHAT WE WERE TALKING ABOUT BEFORE  
12 OUR LUNCH BREAK. WE HAVE FOUR KIND OF POSSIBILITIES  
13 HERE FOR RESOLVING THE ISSUES WE TALKED ABOUT THIS  
14 MORNING, AND THEY'RE LISTED IN DECREASING  
15 RESTRICTIVENESS.

16 SO THE FIRST ONE WHICH I WANTED TO AT LEAST  
17 HAVE US CONSIDER IS FOR CIRM-FUNDED RESEARCH INTENDED  
18 TO DERIVE COVERED STEM CELL LINES INVOLVING THE  
19 DONATION OF UMBILICAL CORD, CORD BLOOD, OR THE PLACENTA  
20 FOR PURPOSES OTHER THAN AUTOLOGOUS DONATION. THE  
21 CHANGE IS WHO DO YOU GET CONSENT FROM? ONE VERSION IS  
22 CONSENT SHALL BE OBTAINED FROM EACH LEGAL PARENT,  
23 GUARDIAN, AND IDENTIFIED GENETIC PARENT.

24 ACTUALLY, GEOFF, WHAT I MEANT TO SAY, EACH OF  
25 THE PARENT OR GUARDIAN AND FROM BOTH GENETIC PARENTS

1 BECAUSE THAT'S THE MOST RESTRICTIVE, GETTING CONSENT  
2 FROM EVERYBODY.

3 MS. CHARO: SO EVEN THE UNIDENTIFIED PARENTS.

4 MS. LANSING: EVEN IF YOU CAN'T FIND THEM.

5 CHAIRMAN LO: IF YOU CAN'T FIND THEM, YOU  
6 CAN'T USE IT FOR THIS RESEARCH. OR YOU CAN DONATE FOR  
7 A CHILD.

8 F IS A LITTLE LESS RESTRICTIVE.

9 MS. LANSING: THAT CHANGES IT TO YOU HAVE TO  
10 BE ABLE TO FIND THEM. IF YOU CAN'T FIND THEM, WE'RE  
11 ALL RIGHT.

12 CHAIRMAN LO: IF YOU FIND THEM, YOU GOT TO  
13 GET THEIR --

14 MS. LANSING: SO THIS FIRST ONE BASICALLY  
15 IS -- F AND F ARE BASICALLY THE SAME EXCEPT THAT 1 F  
16 BASICALLY SAYS THAT YOU HAVE TO BE ABLE TO FIND THE  
17 GENETIC PARENTS. AND IF YOU CANNOT, YOU CANNOT USE IT  
18 FOR THAT PURPOSE OF RESEARCH. THE SECOND ONE SAYS ONLY  
19 IF YOU CAN FIND THE IDENTIFIED PEOPLE DO YOU HAVE TO  
20 USE IT. IF YOU MADE AN ATTEMPT AND YOU CAN'T, THEN YOU  
21 CAN'T OR --

22 CHAIRMAN LO: THE THIRD VERSION IS CONSENT  
23 SHALL BE OBTAINED JUST FROM EACH LEGAL PARENT AND  
24 GUARDIAN, SO IT ALLOWS A SINGLE PARENT TO GIVE THE SOLE  
25 CONSENT. IS THAT CORRECT, THE CORRECT INTERPRETATION?

1 YOU DON'T HAVE TO DO ANYTHING WITH THE GENETIC PARENTS.  
2 IT'S JUST THE LEGAL REARING PARENT OR PARENTS. AND THE  
3 LEAST RESTRICTIVE IS F 4, WHICH IS CONSENT SHALL BE  
4 OBTAINED FROM THE BIRTH MOTHER, SO THAT LEAVES THE  
5 RAISING FATHER, IF THERE IS ONE, IN F 3.

6 MS. LANSING: AND IT JUST MEANS WHO GIVES  
7 BIRTH.

8 CHAIRMAN LO: YEAH, WHO GIVES BIRTH.

9 MS. LANSING: TELL ME, I'M A LITTLE CONFUSED,  
10 THE LEGAL PARENT OR GUARDIAN, WHOEVER -- THAT DOESN'T  
11 NECESSARILY MEAN THE BIRTH MOTHER BECAUSE YOU COULD BE  
12 THE LEGAL PARENT AND NOT THE BIRTH MOTHER. THAT'S A  
13 VERY COMPLICATED ONE BECAUSE -- JUST SO WE'RE CLEAR,  
14 YOU MIGHT NOT BE THE BIRTH MOTHER AND YOU MIGHT BE THE  
15 LEGAL GUARDIAN.

16 MS. CHARO: FOR WHAT IT'S WORTH, SHERRY,  
17 CALIFORNIA IS THE SINGLE MOST CONFUSING STATE ON  
18 PRECISELY THAT POINT WHEN IT COMES TO STATE LAW.

19 MS. LANSING: OF COURSE. THAT'S WHY I ALWAYS  
20 GET CONFUSED.

21 CHAIRMAN LO: THESE ARE FOUR OPTIONS AND WITH  
22 VARIOUS DEGREES OF RESTRICTIVENESS. I THINK THIS DOES  
23 SORT OF LAY OUT THE SCOPE OF OPTION. I GUESS WHAT I'D  
24 LIKE TO GET IS A SENSE OF THE, AGAIN, OUR COMMITTEE,  
25 OUR SUBCOMMITTEE OF NINE, WHICH OPTIONS -- I THINK THIS

1 IS GOING TO BE UP TO THE ICOC, BUT I THINK IT WOULD  
2 HELP THEM IMMENSELY TO GET OUR THINKING ON THIS AND OUR  
3 SENSE OF WHAT WE WANT.

4 DR. PETERS: LET ME LAY OUT WHAT I THINK ARE  
5 THE REASONINGS FOR TRYING TO MAKE THIS DECISION. I  
6 THINK THERE ARE THREE, AND CORRECT ME IF I'M WRONG,  
7 SHERRY, BUT YOU WANT TO ANTICIPATE POSSIBLE LITIGATION  
8 IN THE FUTURE AND HEAD IT OFF BEFORE IT HAPPENS. THAT  
9 WILL BE ONE CATEGORY. THE SECOND CATEGORY WOULD BE THE  
10 VALUE TO SCIENCE, WHICH CAME UP TOWARDS THE END OF OUR  
11 DISCUSSION EARLIER, THAT WE CAN EXPECT OUR SCIENTISTS  
12 TO WANT TO KNOW THE GENETIC HISTORY OF THE MATERIAL  
13 WITH WHICH THEY'RE WORKING, SO THAT WOULD BE CONSISTENT  
14 WITH THE MORE RESTRICTIVE OF THE ALTERNATIVES. AND  
15 THEN, THIRDLY, AS WE HEARD FROM THE ACLU, THAT WE WOULD  
16 LIKE TO BE CONSISTENT RATHER THAN INCONSISTENT WITH  
17 ESTABLISHED CALIFORNIA LAW.

18 NOW, THOSE ARE THE THREE AREAS OF REASONING  
19 THAT I'VE HEARD. AM I MISSING ANY OF THE IMPORTANT  
20 ONES?

21 MS. LANSING: AND CALIFORNIA LAW IS JUST THE  
22 BIRTH MOTHER, CORRECT?

23 DR. PETERS: THAT'S RIGHT.

24 MR. SHEEHY: THANKS FOR LAYING THAT OUT SO  
25 CLEARLY. THAT WAS FANTASTIC. I THINK THE SECOND ONE

1 IS A FALSE CHOICE. SO THE VALUE OF -- SCIENTIFIC VALUE  
2 WILL BE ANSWERED WHEN THE GRANTS ARE REVIEWED. SO TO  
3 SUGGEST THAT WE NEED TO MAKE AN ETHICAL STANDARD -- IN  
4 OTHER WORDS, IF THE PURPOSE OF THE GRANT APPLICATION IS  
5 TO DERIVE A STEM CELL LINE THAT'S GOING TO BE USED FOR  
6 TRANSPLANTATION AND THEY'RE NOT GOING TO HAVE -- AND IN  
7 THAT GRANT APPLICATION IS THE PROPOSAL FOR OBTAINING  
8 THE STEM CELLS, THE CORD BLOOD AND THERE'S NO  
9 INDICATION THAT THEY'RE GOING TO IDENTIFY BOTH GAMETES,  
10 THEN IT'S GOING TO DISQUALIFY THAT. SCIENTIFICALLY  
11 IT'S NOT GOING TO BE A SOUND PROPOSAL.

12 SO THE SCIENTIFIC RATIONALE TO PUT THIS AS AN  
13 ETHICAL STANDARD IS KIND OF BACKWARDS. AND SO I THINK  
14 THAT THE SCIENTIFIC RISK ISN'T REALLY THERE. TO ME THE  
15 MOST COMPELLING PROBLEM, MOST COMPELLING RISK IS  
16 INTERFERENCE WITH -- IS PUTTING SOMETHING INTO  
17 SOMETHING APPROXIMATING STATUTE THAT INTERFERES WITH  
18 EXISTING STATE PROCESSES AND LAWS RELEVANT TO A WOMAN'S  
19 RIGHT TO CONTROL WHAT HAPPENS WITH HER OWN BODY. I  
20 THINK TO POSE A SCIENTIFIC RISK, WHICH I THINK WILL BE  
21 ADDRESSED BY THE SCIENTISTS IN THE CONTEXT OF  
22 SCIENTIFIC REVIEW, DOESN'T REALLY ON THE SCALE BALANCE  
23 OUT AGAINST THE RISK TO WHAT IS AN ESTABLISHED AND  
24 REALLY BECOMES MORE AND MORE OF AN ATTACK ON A PERSONAL  
25 RIGHT OF A WOMAN.

1 MS. LANSING: I HAVE A QUESTION. STATE LAW  
2 SAYS -- THE ACLU WAS SAYING YOU ONLY NEED THE BIRTH  
3 MOTHER.

4 MR. SHEEHY: I'D LIKE -- THEIR LETTER IS  
5 RIGHT HERE. I THINK IT'S PROBABLY THE BEST WAY TO KIND  
6 OF -- OKAY. LET'S JUST -- LET'S JUST -- I CAN JUST  
7 READ THE RELEVANT PARTS OF THIS. "FIRST, THERE'S NO  
8 SUCH THING AS A PARENT OR GUARDIAN OF AN UMBILICAL  
9 CORD, CORD BLOOD, OR A PLACENTA."

10 THEN SHE GOES, THERE'S A DISCUSSION ABOUT  
11 PROGENITOR.

12 "THIRD, REQUIRING PERMISSION FROM ANYONE  
13 OTHER THAN THE PREGNANT WOMAN FOR HER TO DONATE THE  
14 BY-PRODUCTS OF HER PREGNANCY IS COMPLETELY INCONSISTENT  
15 WITH HER SOLE RIGHT TO CHOOSE WHETHER TO TERMINATE THE  
16 PREGNANCY WITH THE RIGHT TO MAKE THIS CHOICE WITHOUT  
17 INFORMING ANYONE ELSE, IF SHE SO CHOOSES. REQUIRING  
18 THAT SHE IDENTIFY A PARTNER AND THAT CONSENT FOR THE  
19 DONATION BE SOUGHT FROM ANY PARTNER VIOLATES HER RIGHT  
20 TO INFORMATIONAL PRIVACY AND THREATENS HER  
21 CONSTITUTIONAL RIGHT TO MAKE DECISIONS REGARDING HER  
22 BODY WITHOUT INTERFERENCE.

23 "MOREOVER, THIS PROVISION IS AS A PRACTICAL  
24 MATTER CERTAIN TO LEAD TO DELAY AND CONFUSION AS WOMAN,  
25 DOCTORS, AND RESEARCHERS ATTEMPT TO DETERMINE WHO MUST

1 BE NOTIFIED AND WHOSE CONSENT MUST BE OBTAINED." SO --

2 DR. KIESSLING: JEFF, AS MUCH AS I APPRECIATE  
3 THE WOMEN'S ISSUES HERE, WE'RE TALKING ABOUT A VERY  
4 SPECIFIC CASE IN WHICH THE CORD BLOOD, WHICH IS REALLY  
5 NOT REALLY HER BODY, THE CORD BLOOD GOING TO BE USED TO  
6 DERIVE STEM CELLS FOR POSSIBLE THERAPY. IT'S THAT VERY  
7 NARROW WINDOW THAT WE'RE TRYING TO BE VERY CONSERVATIVE  
8 ABOUT THE PERSON WHO THE OTHER HALF OF THAT BEING  
9 INVOLVED. NOT JUST FOR RESEARCH IN GENERAL, NOT JUST  
10 FOR THERAPEUTIC PURPOSES, NOT FOR ANYTHING ELSE SHE  
11 WOULD WANT TO DO, BUT FOR THE SPECIFIC PURPOSE OF  
12 DERIVING A LINE OF STEM CELLS FOR POSSIBLE THERAPIES.

13 MR. SHEEHY: START TALKING ABOUT FETAL  
14 TISSUE.

15 DR. PRIETO: THIS IS ANOTHER STANDARD. THIS  
16 IS A SEPARATE STANDARD, AND I THINK THAT --

17 MR. SHEEHY: WHY?

18 DR. PRIETO: BECAUSE WE'RE TALKING ABOUT CORD  
19 BLOOD, AND PLACENTA IS THE ISSUE.

20 MR. SHEEHY: WELL, THE PRINCIPLE HERE IS THE  
21 GENETIC MATERIAL, AND THE GENETIC MATERIAL OF THE  
22 PATERNAL PROVIDER, THE INTEREST IS THE SAME. YOU'RE  
23 JUST AT A DIFFERENT POINT IN THE PROCESS, BUT THE  
24 INTEREST IS THE SAME WITH FETAL TISSUE AS IT IS WITH  
25 CORD BLOOD OR PLACENTA OR UMBILICAL CORD. YOUR

1 INTEREST HERE IS BASED ON THE FACT THAT YOUR GENETIC  
2 MATERIAL IS GOING TO BE USED FOR A THERAPY, AND YOU  
3 HAVEN'T HAD A RIGHT TO SAY ANYTHING ABOUT IT. SO THAT  
4 WOULD COME INTO PLAY WITH FETAL TISSUE. THE LOGIC  
5 WOULD SUGGEST THAT YOU'D HAVE TO PUT THE SAME PROVISION  
6 IN FOR FETAL TISSUE.

7 DR. KIESSLING: IF YOU'RE GOING TO DERIVE A  
8 LINE.

9 MR. SHEEHY: IF YOU ARE GOING TO DERIVE A  
10 LINE, EXACTLY. AND THEN YOU WOULD HAVE TO --

11 DR. KIESSLING: YOU'RE GOING TO DERIVE A LINE  
12 OF CELLS.

13 DR. PRIETO: IF YOU'RE DERIVING A LINE, EVEN  
14 WELL BEFORE YOU GET TO THE POINT OF THINKING ABOUT THIS  
15 AS SOME SORT OF THERAPY, YOU STILL HAVE TO CONSIDER THE  
16 RIGHTS OF ANY PARTY INVOLVED, ANY PARTY WITH A  
17 LEGITIMATE INTEREST, WITH WHAT WE WOULD CONSIDER ON  
18 ETHICAL GROUNDS TO HAVE A LEGITIMATE INTEREST IN WHAT  
19 IS DONE WITH THEIR GENETIC MATERIAL.

20 MR. SHEEHY: BUT IF YOU LOOK AT GENETIC  
21 MATERIAL VERSUS AN ACTUAL HUMAN BEING, WHICH WE HAVE IN  
22 THE INSTANCE OF A FETUS, I THINK THE GENETIC MATERIAL  
23 ON THE SCALE IS MUCH LESS WEIGHTY THAN A FETUS. AND  
24 YET WE DON'T REQUIRE THE PERMISSION OF THE FATHER WHEN  
25 WE'RE GOING TO HAVE A TERMINATION OF THE PREGNANCY.



1 DR. PRIETO: BUT THERE'S A DIFFERENT ISSUE.  
2 THE DIFFERENT ISSUE IS WHAT YOU'RE COMPELLING THAT  
3 WOMAN TO DO.

4 MR. SHEEHY: WE WILL HAVE ESTABLISHED THE  
5 PRINCIPLE. I THINK YOU HAVE TO UNDERSTAND THAT THE  
6 LOGIC, WE'RE CREATING A LOGICAL TRAIN OF THOUGHT THAT  
7 LEADS DOWN A CERTAIN ROAD. AND TO ME THAT'S WHAT IT  
8 LOOKS LIKE.

9 DR. OLDEN: IN CALIFORNIA DOES A WOMAN HAVE A  
10 RIGHT TO DECIDE TO DONATE FETAL TISSUE FOR THE PURPOSE  
11 OF DERIVING A CELL LINE WITHOUT THE -- AREN'T THERE  
12 LAWS ABOUT THAT IN TERMS OF WHO MUST BE CONSENTED? AND  
13 THAT'S -- I THINK THAT'S THE COMPARISON AND NOT ABOUT  
14 ABORTING THE FETUS IS NOT A PERFECT COMPARISON.

15 CHAIRMAN LO: THERE'S ANOTHER COMPARISON, AND  
16 THAT'S THE ADULT -- THE DONOR OF SOMATIC CELLS FOR  
17 SOMATIC CELL NUCLEAR TRANSFER. WE REQUIRE CONSENT FROM  
18 THAT PERSON, EVEN THOUGH THE RISK IS MINIMAL. AND WE  
19 COULD PROBABLY GET THE TISSUE WITHOUT THEIR EVEN  
20 KNOWING IT IN SOME SITUATIONS FROM LEFT-OVER TISSUE.  
21 WE DON'T ALLOW THAT EVEN THOUGH IT IS MINIMAL RISK AND  
22 YOU CAN ANONYMIZE IT BECAUSE WE SAY THAT THERE'S --  
23 THIS IS SUCH AN UNUSUAL USE OF YOUR TISSUE, FAR BEYOND  
24 OTHER THINGS, THAT AS A MATTER OF RESPECT TO YOU AS AN  
25 INDIVIDUAL, WE WANT YOU TO GIVE US PERMISSION TO DO

1 THIS PARTICULAR THING.

2 SO I THINK, YOU KNOW, AS TED LAID IT OUT,  
3 IT'S NOT JUST TO FORESTALL COMPLAINTS FROM GENETIC  
4 PARENTS, BUT IT'S RESPECTING THE RIGHT OF PEOPLE TO  
5 CONTROL WHAT IS DONE WITH BODILY TISSUE THAT THEY MAY  
6 REGARD AS SPECIAL AND SENSITIVE FOR PURPOSES THEY MAY  
7 REGARD AS SENSITIVE PURPOSES.

8 DR. KIESSLING: IS THERE A WAY THAT THIS CAN  
9 BE WORDED SO THAT IT SPEAKS TO JEFF'S CONCERNS? HE'S  
10 CONCERNED ABOUT OPENING A DOOR THAT'S NOW NOT OPEN.

11 MS. LANSING: WELL --

12 CHAIRMAN LO: IS THERE A WAY OF ADDRESSING  
13 IT? I WOULD CERTAINLY SAY THIS IS A LIMITED -- THIS  
14 DOES NOT HAVE ANYTHING TO DO WITH OTHER DECISIONS THAT  
15 A WOMAN CAN MAKE.

16 MS. LANSING: WE CAN ADD THAT SENTENCE.

17 DR. TAYLOR: ONLY RESEARCH FOR THE PURPOSE OF  
18 DERIVING STEM CELL LINES ARE THESE REQUIREMENTS  
19 MANDATED. BECAUSE WE'VE --

20 MS. LANSING: WE'VE DONE THINGS WITH OUR  
21 INFORMED CONSENT WHICH IS AGAINST THE WOMAN'S RIGHT FOR  
22 AN ABORTION. WE HAVE, LIKE, A WAITING PERIOD.

23 MR. SHEEHY: THAT'S A DIFFERENT KETTLE OF  
24 FISH.

25 MS. LANSING: NO, BUT I'M SAYING WE --

1 BECAUSE I WAS VERY MINDFUL OF TRYING TO KIND OF SEE IF  
2 WE COULD CONFORM TO STATE LAW, WHATEVER. BUT I AGREE  
3 WITH WHAT BERNIE'S SAYING, AT THIS TIME. AND I COME  
4 BACK TO THIS COMPELLING THING THAT AS OF YET, NO ONE'S  
5 SHOWING ME, AND THEY MAY, YOU KNOW, SHORTLY, SHOW ME  
6 THAT WE'RE NOT GETTING ENOUGH AND THAT WE DON'T HAVE  
7 ENOUGH TO DO THE RESEARCH ON, AND THEN I WOULD SAY WE  
8 SHOULD REALLY REEXAMINE THIS.

9 MR. SHEEHY: WELL, IT SEEMS TO ME ALMOST AS A  
10 PRACTICAL MATTER THAT IT'S NOT GOING TO BE  
11 SCIENTIFICALLY RATIONAL TO DEVELOP STEM CELL LINES  
12 UNLESS YOU HAVE THE IDENTITY OF BOTH GAMETES, BUT THAT  
13 IS A SCIENTIFIC QUESTION. TO MAKE THAT AN ETHICAL  
14 QUESTION WITH ITS OVERFLOW INTO THIS OTHER AREA IS VERY  
15 WORRISOME TO ME BECAUSE WE'RE POSITING CERTAIN RIGHTS  
16 THAT DON'T EXIST RIGHT NOW. AND I JUST THINK WE NEED  
17 TO BE VERY CAREFUL BEFORE WE DO THAT.

18 CHAIRMAN LO: ALTA, IS THERE A WAY WE CAN  
19 ADDRESS JEFF'S CONCERNS ABOUT 1 F OR 2 F BY MAKING  
20 CLEAR IN THE LANGUAGE THIS HAS NO IMPLICATIONS  
21 WHATSOEVER FOR OTHER DECISIONS REGARDING THE WOMAN'S  
22 RIGHT TO MAKE REPRODUCTIVE, BIRTHING, AND CHILDREARING  
23 DECISIONS?

24 MS. CHARO: YES. IT'S QUITE COMMON IN  
25 LEGISLATIVE DRAFTING AND WRITING A PROVISION TO THEN

1 SAY, NOTWITHSTANDING THIS PROVISION, NOTHING HERE SHALL  
2 BE INTERPRETED TO AFFECT EXISTING RULES CONCERNING  
3 CONSENT TO DONATE PLACENTA, CORD, OR CORD BLOOD FOR  
4 AUTOLOGOUS OR FOR THERAPEUTIC PURPOSES, WHATEVER. WE  
5 HAVE TO WORK ON CAPTURING THE LANGUAGE, BUT YOU AN  
6 ABSOLUTELY PUT SOMETHING IN THERE THAT SAYS THAT.

7 MR. SHEEHY: I AGREE WITH FOR AUTOLOGOUS  
8 PURPOSES. WHAT I'M WORRIED ABOUT IS THAT WE'RE GOING  
9 TO SUGGEST THAT THIS PRODUCT OF PREGNANCY, THIS  
10 INTEGRAL PRODUCT OF PREGNANCY NO LONGER BELONGS TO THE  
11 WOMAN. IT BELONGS EQUALLY TO HER NOW PARTNER WHEN THE  
12 PREGNANCY AT THIS TIME DOES NOT.

13 MS. CHARO: ALL OF THIS IS POST PREGNANCY,  
14 RIGHT. SO --

15 MR. SHEEHY: BUT THE POINT, I THINK -- I  
16 DON'T KNOW IF YOU WERE HERE. WOULDN'T THIS NOT APPLY  
17 TO FETAL TISSUE AS WELL? HOW CAN WE MAKE THIS -- WHERE  
18 DOES THE DISTINCTION COME THAT POST PREGNANCY IS  
19 SUDDENLY DIFFERENT FROM FETAL TISSUE?

20 DR. KIESSLING: FOR ONE THING, THIS  
21 INDIVIDUAL --

22 MR. SHEEHY: WOULDN'T WE NOT WANT, IF WE WERE  
23 GOING TO DERIVE STEM CELLS FROM FETAL TISSUE IDENTITY,  
24 AND WOULD THAT NOT INVOLVE NECESSITATING THE  
25 IDENTIFICATION?

1                   CHAIRMAN LO:  JEFF, IF YOU ARTICULATED ALL  
2                   THE POSSIBLE IMPLICATIONS OR THE MAJOR IMPLICATIONS  
3                   THAT THIS COULD HAVE FOR OTHER WOMAN'S DECISION-MAKING  
4                   RIGHTS, EXPLICITLY USE ALTA'S NOTWITHSTANDING THIS  
5                   PROVISION, NOTHING IN THIS CLAUSE SHALL BE DEEMED TO  
6                   COMPROMISE THE WOMAN'S RIGHT TO CHOOSE WHETHER OR NOT  
7                   TO TERMINATE PREGNANCY OR THE WOMAN'S RIGHT TO CHOOSE  
8                   MEDICAL CARE FOR HER CHILD.  WE CAN LIST ALL THE THINGS  
9                   THAT YOU'RE CONCERNED ABOUT AND ANY OTHER RIGHTS THAT  
10                  THE WOMAN CURRENTLY HAS UNDER CALIFORNIA LAW.  I WOULD  
11                  DEFER TO A LAW PERSON TO HELP US DRAFT THAT TO TRY AND  
12                  SAY THIS IS REALLY SOMETHING SPECIAL, AND WE REALLY  
13                  DON'T WANT THIS TO WORK BACKWARDS TO UNDERMINE A  
14                  WOMAN'S RIGHT TO CHOOSE TO TERMINATE PREGNANCY.

15                  MS. LANSING:  REALLY WHEN YOU DO IT THE  
16                  OPPOSITE WAY, THOUGH, I THINK, AS YOU SAY, I CAN'T DO  
17                  LANGUAGE, BUT IT'S LIKE THIS IS THE SOLE EXEMPTION AND  
18                  ALL THE OTHER RIGHTS THAT A WOMAN HAS IN HER PREGNANCY  
19                  REMAIN INTACT, AND WE ARE BY NO MEANS --

20                  MR. SHEEHY:  I HAVE TO SAY THE ONLY ONE I CAN  
21                  SUPPORT IS F WITHOUT FEEDBACK FROM ACLU AND PEOPLE WHO  
22                  WORK IN THIS FIELD.  I JUST AM NOT CONFIDENT THAT WE  
23                  HAVE THE ABILITY TO PUT THE LANGUAGE IN THERE IN A WAY  
24                  TO PROTECT THIS VERY IMPORTANT RIGHT.

25                  MS. CHARO:  THIS IS RISKY FOR ME, AND STOP ME

1 IF I'M REALLY STEPPING ON YOU, BUT THERE IS YET ANOTHER  
2 POSSIBLE APPROACH TO THIS. LET ME JUST TRY THIS OUT.  
3 LET'S SAY YOU START WITH THE FOURTH VERSION, WHICH  
4 TRACKS STATE LAW WITH REGARD TO DISPOSITIONAL AUTHORITY  
5 OVER THESE MATERIALS. START THERE. AND THEN YOU SAY  
6 IN SOME APPROPRIATE LANGUAGE THAT CIRM FUNDING WILL BE  
7 PREFERENTIALLY GIVEN TO PROTOCOLS IN WHICH CONSENT HAS  
8 BEEN ATTAINED AS WELL FROM ALL LEGAL PARENTS AND  
9 GUARDIANS AND GENETIC PARENTS.

10 THE REASON I'M ASKING THIS IS BECAUSE IT  
11 DOESN'T CHANGE THE RULES ABOUT WHO ABSOLUTELY HAS TO  
12 GIVE CONSENT IN ANY WAY, BUT IT TRACKS WHAT WE'VE BEEN  
13 HEARING REPEATEDLY FROM AND ANN FROM ROB AND FROM YOU,  
14 JEFF, ABOUT WHAT, SCIENTIFICALLY SPEAKING, WOULD BE, IN  
15 FACT, PREFERABLE FROM A KIND OF TECHNICAL ASSESSMENT OF  
16 THE PROTOCOL ANYWAY, WHICH IS YOU WANT AS MUCH  
17 INFORMATION AS POSSIBLE. ANN WAS SAYING EARLIER THAT  
18 IT'S SO HARD TO DERIVE A NEW LINE, THAT YOUR BEST  
19 PRACTICES WOULD ALWAYS BE PRACTICES IN WHICH YOU WANT  
20 ASSURANCE ABOUT GENETIC PARENTAGE IN ORDER TO HAVE  
21 MAXIMAL INFORMATION.

22 SO IS IT INAPPROPRIATE TO WRITE INTO ETHICAL  
23 STANDARDS THAT THERE'S A FUNDING PREFERENCE FOR ONE  
24 THING OVER ANOTHER EVEN THOUGH IT'S NOT REQUIRED TO BE  
25 THAT WAY?

1           MR. SHEEHY: I ALMOST MIGHT SAY THAT MIGHT  
2 ASK FOR SCIENTIFIC JUSTIFICATION FOR NOT REQUIRING  
3 THAT. ACTUALLY THAT MIGHT BE THE WAY TO SKIN THIS CAT.  
4 BUT THE WAY -- I MIGHT EVEN MAKE IT STRONGER. I WOULD  
5 THINK THAT IF CIRM-FUNDED RESEARCH SHOULD -- I DON'T  
6 HAVE THE PRECISE LANGUAGE, BUT I WOULD SAY THAT WE  
7 COULD PUT THE REQUIREMENT THAT THEY HAVE TO PRODUCE A  
8 SCIENTIFIC RATIONALE WHY THEY DIDN'T NEED  
9 IDENTIFICATION OF BOTH GAMETES IN ORDER TO DO THIS. IN  
10 OTHER WORDS, TAKE IT -- BECAUSE THERE ISN'T A GOOD  
11 SCIENTIFIC RATIONALE, I THINK, IF YOU'RE GOING TO  
12 DERIVE A STEM CELL LINE, NOT TO HAVE, ESPECIALLY WITH  
13 THERAPY AS YOUR GOAL, NOT TO HAVE BOTH LINES. BUT I  
14 THINK WE CAN MAKE IT EVEN STRONGER WITH THE WORK DOWN  
15 THE ROAD, I GUESS.

16           MS. LANSING: WHAT ABOUT THIS? I DON'T KNOW.  
17 YOU SAY IN COMPLIANCE WITH STATE LAW. I'M GOING TO BE  
18 REALLY SPECIFIC. IN COMPLIANCE WITH STATE LAW, AND YOU  
19 GO TO FOUR, DO YOU KNOW, BASICALLY, COMPLIANCE WITH  
20 STATE LAW. HOWEVER, I'M TAKING WHAT YOU'RE SAYING.  
21 HOWEVER, FOR CIRM-FUNDED CORD BLOOD RESEARCH, WE WANT  
22 X, X, X, AND X AND X AND X. I WOULDN'T EVEN SAY  
23 PREFERABLE BECAUSE I'M TAKING WHAT YOU'RE SAYING  
24 BECAUSE YOU'RE NOW COMING -- BECAUSE NOW WE'RE ALL KIND  
25 OF COMING TO THE SAME PLACE.

1 MR. SHEEHY: WE'RE COMING BACK -- WE'RE  
2 SAYING BECAUSE WE'RE GOING TO THE SCIENTIFIC QUESTION.

3 MS. LANSING: FOR THE BEST -- HOWEVER, FOR  
4 CIRM-FUNDED CORD BLOOD RESEARCH, WE WANT -- WE MUST  
5 HAVE THESE, THESE, THESE, AND THESE. THEN WE GO TO THE  
6 TOP ONE.

7 CHAIRMAN LO: THERE IS A COMPELLING  
8 SCIENTIFIC REASON NOT TO REQUIRE --

9 MR. SHEEHY: WE SHOULD MENTION THAT THIS IS  
10 PREFERABLE FROM A SCIENTIFIC POINT OF VIEW. WE MAKE IT  
11 A SCIENTIFIC QUESTION INSTEAD OF AN ETHICAL QUESTION.

12 MS. LANSING: HERE'S WHAT I'M ASKING WHY --  
13 WE'RE SPLITTING HAIRS. I'M RECOMMENDING THIS IS AS A  
14 GOOD SOLUTION. LIKE EVERYBODY GETS WHAT THEY WANT. WE  
15 START WITH -- I THINK IT'S FAIR. I UNDERSTAND WHAT  
16 EVERYBODY IS SAYING. WE START WITH 4 F, OKAY, BUT YOU  
17 SAY IN COMPLIANCE WITH STATE LAW. OKAY. THAT'S GOOD.  
18 CURRENT STATE LAW. AND YOU BASICALLY GO THAT SENTENCE.  
19 HOWEVER, STEM CELL -- CIRM, YOU KNOW, REQUIRES, DO YOU  
20 KNOW, THAT WE HAVE, AND THEN YOU GO TO 1 F, WHICH IS  
21 THE TOUGHEST ONE, PERIOD. WHY DO YOU HAVE TO SAY  
22 UNLESS THERE'S COMPELLING SCIENTIFIC EVIDENCE? IN  
23 OTHER WORDS, START WITH THAT. THEN WHEN WE FIND OUT  
24 THAT IT DOESN'T WORK, WE COME BACK AND ADD UNLESS  
25 THERE'S COMPELLING SCIENTIFIC EVIDENCE TO THE CONTRARY.



1 I'M, LIKE, SAYING TO YOU THIS ISN'T IN STONE  
2 FOR THE NEXT TEN YEARS, AND THEN WE'RE SITTING HERE SIX  
3 MONTHS FROM NOW AND WE FIND THERE'S COMPELLING  
4 SCIENTIFIC EVIDENCE WHY WE CAN'T GET IT OR WE CAN'T GET  
5 CELL LINES, THEN WE COME BACK AND ADD THAT SENTENCE OR  
6 WE CHANGE IT.

7 MR. SHEEHY: I WANT THE SCIENTIFIC RATIONALE  
8 TO BE THE RATIONALE WHY WE REQUIRED THIS AS OPPOSED TO  
9 AN ETHICAL. THESE ARE ETHICAL -- THIS IS AN ETHICAL  
10 THING. I DON'T THINK THAT WE WANT TO BE IN A POSITION  
11 OF MAKING AN ETHICAL JUDGMENT ABOUT THE WOMAN'S CONTROL  
12 OF HER BODY, BUT WE CAN REFERENCE THE SCIENTIFIC  
13 RATIONALE. AND BY REFERENCING THAT, WE INOCULATE  
14 OURSELVES AGAINST HAVING MADE THIS ETHICAL DECISION  
15 THAT'S CONTRARY.

16 MS. LANSING: BUT THEN YOU CAN SAY, HOWEVER,  
17 IN THE CASE OF CIRM-FUNDED RESEARCH.

18 DR. KIESSLING: SPECIFICALLY INTENDED TO  
19 DERIVE.

20 MS. LANSING: FROM THE BLOOD WE, BECAUSE OF  
21 THE BEST PRACTICE OF SCIENCE, DEMAND THE FOLLOWING. SO  
22 SOMEBODY WRITE THAT.

23 MS. CHARO: I'M JUST TRYING TO UNDERSTAND.  
24 WHERE WE ARE NOW AT IS WE'RE GOING TO BREAK THIS INTO  
25 TWO SEPARATE PROVISIONS, RIGHT. SO THE FIRST WILL BE

1 FOR CIRM-FUNDED RESEARCH INTENDED TO DERIVE COVERED  
2 STEM CELL LINES INVOLVING THE DONATION OF UMBILICAL  
3 CORD, CORD BLOOD, OR PLACENTA. FOR PURPOSES OF  
4 AUTOLOGOUS DONATION, CONSENT SHALL BE OBTAINED AS  
5 PURSUANT TO STATE LAW, WHICH WE'LL KEEP IT ALWAYS  
6 CURRENT WITH WHATEVER THAT IS.

7 MS. LANSING: HOW ABOUT FOR CIRM-FUNDED  
8 RESEARCH IN COMPLIANCE WITH STATE LAW.

9 MS. CHARO: RIGHT. AND THAT'S FOR THE  
10 AUTOLOGOUS TRANSPLANTATION. AND THEN THE NEXT ONE  
11 WOULD BE THE SAME EXCEPT FOR PURPOSES OTHER THAN  
12 AUTOLOGOUS DONATION, CONSENT SHALL BE OBTAINED FROM  
13 EACH LEGAL PARENT, GUARDIAN -- AND ALL LEGAL PARENTS,  
14 GUARDIANS, AND GENETIC PARENTS. RIGHT. AM I GETTING  
15 IT RIGHT?

16 MS. LANSING: YES. BUT THE DIFFERENCE IS THE  
17 4 F ONE, WHICH IS THE FIRST ONE THAT SAYS IN COMPLIANCE  
18 WITH STATE LAW, CIRM-FUNDED RESEARCH INTENDED TO  
19 DERIVE --

20 MS. CHARO: FOR AUTOLOGOUS DONATION.

21 MS. LANSING: AND THEN THE SECOND ONE, WHICH  
22 IS 1 F, IS BASICALLY SAYING, HOWEVER, FOR CIRM-FUNDED  
23 RESEARCH IN COMPLIANCE --

24 MS. CHARO: SHERRY, THERE WHAT WE MIGHT WANT  
25 TO SAY IS FOR THE CIRM-FUNDED RESEARCH FOR PURPOSES

1 OTHER THAN AUTOLOGOUS DONATION, CONSENT SHALL, IN  
2 ADDITION, BE OBTAINED FROM ALL LEGAL PARENTS, GENETIC  
3 PARENTS, AND GUARDIANS.

4 MS. LANSING: IN ORDER TO OBTAIN THE BEST  
5 SCIENCE. THAT'S WHAT WE'RE TRYING TO SAY.

6 MR. SHEEHY: WE HAVE TO MAKE THE SCIENTIFIC  
7 TOUCHDOWN IN ORDER TO PROVIDE THE BEST.

8 CHAIRMAN LO: AS I UNDERSTAND IT, JEFF IS IN  
9 AGREEMENT WITH PROVIDING WE SAY EXPLICITLY IN F 1 THAT  
10 IT'S SCIENCE.

11 (SIMULTANEOUS VOICES.)

12 MS. LANSING: IN ORDER TO ATTAIN THE HIGHEST  
13 SCIENTIFIC STANDARDS OR TO MAINTAIN THE BEST SCIENCE.  
14 SO GEOFF AND ALTA, CAN YOU WRITE THIS UP?

15 MS. CHARO: HE'S ALREADY WORKING ON IT.

16 DR. PRIETO: I FEEL A LITTLE DISCOMFORT WITH  
17 COMPLETELY SIDE-STEPPING THE ETHICAL ISSUES SINCE I  
18 THINK THAT IS SORT OF OUR BRIEF. NEVERTHELESS, I  
19 UNDERSTAND THE PROBLEMS, AND I DON'T THINK WE'LL GET TO  
20 RESOLUTION OTHERWISE. AND I CAN SEE, RATHER THAN THE  
21 FIRST VERSION, BOTH GENETIC PARENTS, I CAN SEE  
22 SITUATIONS IN WHICH SCIENTIFIC, VALID, WORTHWHILE  
23 SCIENTIFIC RESEARCH COULD TAKE PLACE, PERHAPS NOT  
24 DERIVING A CELL LINE THAT WOULD BE USEFUL FOR  
25 TRANSPLANTATION OR IMPLANTATION, BUT FOR LEARNING

1 SOMETHING VALUABLE WITHOUT BOTH GENETIC PARENTS  
2 NECESSARILY BEING IDENTIFIABLE.

3 SO THE SECOND -- THE WORDING OF THE SECOND  
4 VERSION, I THINK IT WOULD BE A LITTLE BIT LESS  
5 RESTRICTIVE AND PREFERABLE TO ME.

6 MS. LANSING: I DON'T THINK YOU WANT TO LIMIT  
7 IT WHEN WE START AND --

8 CHAIRMAN LO: I WOULD LIKE TO PRESENT THIS AS  
9 A COMPROMISE -- I WOULD LIKE TO PRESENT THIS TO THE  
10 ICOC AS A COMPROMISE, THAT THERE WERE VERY IMPORTANT  
11 ETHICAL CONSIDERATIONS AT STAKE WHICH PULL US IN  
12 DIFFERENT DIRECTIONS. THAT'S WHAT MAKES THIS TOUGH.  
13 AND WE WANTED TO BOTH TRY AND BE ATTENTIVE TO JEFF'S  
14 CONCERNS THAT WE DO NOT UNDERMINE AND OTHER PEOPLE'S  
15 CONCERNS THAT WE DO NOT UNDERMINE WOMEN'S RIGHTS IN  
16 DECISION MAKING SURROUNDING REPRODUCTIVE AND  
17 OBSTETRICAL. ON THE OTHER HAND, WE ALSO WANT TO NOT  
18 USE PEOPLE'S DNA IN WAYS THAT THEY MIGHT HAVE WELL  
19 OBJECTED TO WITHOUT THEIR EXPLICIT CONSENT. THE  
20 TRADE-OFF IS TO DO THE FIRST, WE'RE SORT OF SAYING  
21 REASONS FOR THE SECOND THAT ARE DIFFERENT, FOR EXAMPLE,  
22 FROM WHAT I WOULD HAVE SAID, BUT, YOU KNOW, JUST SO WE  
23 DON'T HAVE A CASCADE EFFECT ON OTHER PARENTING RIGHTS.  
24 I WOULD DOWNPLAY THE RIGHT TO HAVE -- TO NOT HAVE  
25 TISSUE, IT'S NOT GOOD SCIENCE, WHICH IS TRUE. I THINK

1 IT'S A WAY OF TRYING TO HAVE BOTH SIDES SATISFIED WITH  
2 THE RESOLUTION; WHEREAS, IF WE PUSHED IT TOO MUCH ONE  
3 WAY OR THE OTHER, I THINK YOU WOULD LOSE WHAT WE NOW  
4 HAVE AS A POSSIBLE.

5 I THINK, YOU KNOW, I'D BE WILLING TO MOVE  
6 FROM WHAT I WOULD HAVE DONE BECAUSE I THINK JEFF AND  
7 OTHERS HAVE EXPRESSED REAL CONCERNS. WHATEVER WE WANT  
8 TO WRITE IN ALTA'S SORT OF LEGALESE LANGUAGE IS SAY  
9 NOTWITHSTANDING THE IMPLICATIONS FOR ANYTHING ELSE, AND  
10 I THINK WE SHOULD PROBABLY ASK ALTA TO DRAFT THAT  
11 LANGUAGE AND PUT IT IN AND MAKE IT EVEN STRONGER. I'M  
12 SATISFIED WITH THIS BECAUSE, IN FACT, YOU END UP  
13 GETTING CONSENT. YOU'RE NOT GOING TO USE TISSUE  
14 WITHOUT THE CONSENT OF BOTH GENETIC PARENTS.

15 I THINK IT'S MORE IMPORTANT TO GET THAT  
16 RATHER THAN TO GET THE REASONS FOR IT. THIS CAN  
17 CHANGE. IF OTHER THINGS COME UP, IF THE SCIENCE  
18 CHANGES, WE'RE NOT GETTING ENOUGH MATERIALS TO USE FOR  
19 DERIVATION OF CORD STEM CELLS, I THINK WE CAN REVISIT  
20 THIS.

21 DR. KIESSLING: ARE WE GOING TO END UP WITH  
22 JUST ONE VERSION TO POST?

23 CHAIRMAN LO: I WOULD TRY. I'D LIKE TO. I'D  
24 LIKE TO. AGAIN, I THINK WE'RE GOING TO HAVE PEOPLE  
25 OBJECTING AT BOTH ENDS, BUT I THINK IF WE CAN SAY THIS

1 IS SOMETHING THAT WE CAN LIVE WITH, WE'D RATHER DO THAT  
2 THAN SAY HERE ARE FOUR, PICK ONE. IF ALTA IS GOING TO  
3 COME UP WITH LANGUAGE OF SORT OF NOTWITHSTANDING WHAT  
4 WE'RE SAYING THAT SAYS NO IMPLICATIONS FOR ANYTHING  
5 ELSE IN THE WORLD.

6 ANY PUBLIC COMMENTS ON THIS?

7 MR. SIMPSON: I MYSELF FAVOR NO. 4, BUT I  
8 THINK YOU'RE CRAFTING A REASONABLE COMPROMISE.

9 CHAIRMAN LO: WHILE WE'RE AT IT, I THINK  
10 WE'VE RESOLVED THIS, WHICH MEANS WHILE WE'RE WAITING  
11 FOR ALTA TO CRAFT THE LANGUAGE, THERE'S ONE MORE ISSUE  
12 THAT WE SHOULD DEAL WITH, IF POSSIBLE. AND I AM  
13 MINDFUL THAT I HAVE A 7 O'CLOCK PLANE, SO I'M TRYING TO  
14 WRAP THIS UP BY A QUARTER OF FIVE AT THE LATEST.

15 THE ISSUE OF COMPENSATION TO OOCYTE DONORS IN  
16 CIRM-FUNDED RESEARCH FOR LOST WAGES. SO HERE'S THE --  
17 AS YOU ARE AWARE, THAT WAS WHAT WE DECIDED LAST TIME ON  
18 THE PRINCIPLE THAT IF A WOMAN ACTUALLY LOST WAGES BY  
19 SORT OF COMING IN AND DONATING OOCYTES, WE'D WANT TO  
20 COMPENSATE HER BACK TO WHERE SHE WOULD HAVE BEEN, SO  
21 SHE DOESN'T ACTUALLY END UP BEING WORSE OFF FOR  
22 PARTICIPATING IN RESEARCH AS A REASONABLE EXPENSE.

23 SENATOR ORTIZ HAS A BILL TO FORBID THAT IN  
24 CALIFORNIA, THAT YOU CAN'T COMPENSATE FOR LOST WAGES IN  
25 OOCYTE DONATION. OTHER MEMBERS OF THE PUBLIC HAVE ALSO

1 OBJECTED TO COMPENSATING LOST WAGES. AND AGAIN, THIS  
2 REFERS TO THE PRO-CHOICE ALLIANCE FOR RESPONSIBLE  
3 RESEARCH AND CENTER FOR GENETICS AND SOCIETY, AMONG  
4 OTHERS. THEIR PAGE 2 SAY THAT WE SHOULD STRIKE  
5 ACTUALLY LOST WAGES AS A PERMISSIBLE EXPENSE, AND THEY  
6 CITE THAT LOW-INCOME WOMEN ARE LESS LIKELY TO BE GIVEN  
7 PERMISSION BY THEIR EMPLOYERS, SO IT ACTUALLY  
8 DISCRIMINATES AGAINST LOW-INCOME WOMEN WHO WOULDN'T BE  
9 ELIGIBLE FOR COMPENSATION. AND ALSO THEY SAY THAT  
10 THERE'S A PROBLEM WITH IT'S A PERVERSE INCENTIVE TO GET  
11 RESEARCHERS TO FIND LOW-INCOME PEOPLE TO STRETCH THEIR  
12 RESEARCH BUDGETS.

13 SO THOSE ARE THE ARGUMENTS THAT HAVE BEEN PUT  
14 FORTH. OTHERS HAVE ARGUED AGAINST THAT, THAT, IN FACT,  
15 IF YOU HAVE A LOW-INCOME WOMAN WHO, IN FACT, IS LOSING  
16 WAGES, YOU'RE REALLY MAKING HER WORSE OFF BY GIVING HER  
17 A DETRIMENT FROM WHICH SHE MAY FIND IT HARDER TO  
18 RECOVER. SO, AGAIN, THIS IS A COMPLICATED ISSUE.  
19 PEOPLE FEEL STRONGLY ON DIFFERENT SIDES, AND I JUST  
20 WANT TO REVISIT THIS TO SEE IF YOU'RE COMFORTABLE WITH  
21 WHAT WE PROPOSE OR WE NEED TO MODIFY THAT MORE.

22 YOU WANT TO COME BACK TO ALTA'S LANGUAGE?

23 MS. CHARO: YES. THIS IS THE GEOFF AND ALTA  
24 SHOW OVER HERE.

25 CHAIRMAN LO: LET'S DO THIS FIRST, AND IF WE

1 CAN SOLVE THIS, THEN WE'LL GO ON TO THE PAYMENT. PUT  
2 IT UP ON THE SCREEN. NOW WE'RE DOWN TO SEVEN. IT'S  
3 THE SENSE OF THE NINE WISE PEOPLE.

4 MS. CHARO: NEXT TIME MY STUDENTS COMPLAIN  
5 THAT THEY SHOULDN'T HAVE TO TAKE TIMED EXAMS IN LAW  
6 SCHOOL BECAUSE LAWYERS HAVE LOTS OF TIME TO DO THEIR  
7 WORK, WE'LL HAVE AN ANSWER.

8 CHAIRMAN LO: MAKE SOME OF THEM COME TO THESE  
9 MEETINGS.

10 MS. CHARO: YOU WANT TO READ THIS OUT LOUD?  
11 WE HAVE F WITH TWO SUBSECTIONS. CONSISTENT WITH  
12 EXISTING LAW, FOR CIRM-FUNDED RESEARCH THAT USES  
13 UMBILICAL CORD, CORD BLOOD, OR PLACENTA FOR AUTOLOGOUS  
14 DONATION, CONSENT SHALL BE OBTAINED FROM THE WOMAN  
15 GIVING BIRTH. NOTWITHSTANDING F 1 ABOVE, CONSISTENT  
16 WITH SCIENTIFIC RIGOR --

17 MS. LANSING: OH, I LIKE THAT.

18 MS. CHARO: -- FOR CIRM-FUNDED RESEARCH THAT  
19 USES UMBILICAL CORD, CORD BLOOD, OR THE PLACENTA TO  
20 DERIVE COVERED STEM CELL LINES FOR PURPOSES OTHER THAN  
21 AUTOLOGOUS DONATION, CONSENT SHALL BE OBTAINED FROM  
22 EACH LEGAL PARENT, GUARDIAN, AND GENETIC PARENT.

23 MS. LANSING: THANK YOU, GEOFF. THANK YOU,  
24 ALTA. THAT WAS JUST GREAT.

25 CHAIRMAN LO: THAT SOUNDS GREAT TO ME. I



1 JUST WANTED TO ADD DO YOU WANT ANOTHER F (III), SAY  
2 NOTWITHSTANDING WHATEVER WE SAY HERE, WE ARE NOT  
3 UNDERMINING ANY RIGHTS THE WOMAN HAS UNDER  
4 CALIFORNIA --

5 MS. CHARO: OKAY. GEOFF CAN TYPE WHILE WE'RE  
6 DICTATING.

7 MR. LOMAX: I COMMITTED MYSELF TO NOT EVER  
8 DOING THIS.

9 MS. CHARO: F (III), NOTHING IN THIS SECTION  
10 SHALL BE CONSTRUED TO AFFECT STATE OR FEDERAL LAW --

11 CHAIRMAN LO: OR NATURAL LAW.

12 MS. CHARO: -- WITH REGARD TO REPRODUCTIVE  
13 DECISION-MAKING. IS THAT WHAT YOU WANT?

14 CHAIRMAN LO: YES. ANY MORE LEGALESE TO MAKE  
15 IT MORE IMPRESSIVE, I'M ALL FOR IT.

16 MS. LANSING: I'M THRILLED WITH THIS. I HAVE  
17 TO SAY FOR THE RECORD I'M REALLY GLAD WE HUNG IN WITH  
18 THIS BECAUSE THEN WE CAN PRESENT, I HOPE, ANYWAYS, A  
19 UNIFIED POSITION TO THE ICOC. AND I THINK THAT'S MUCH  
20 BETTER THAN GIVING A LOT OF CHOICES.

21 DR. TAYLOR: AS SOMEONE WHO OPINED THAT WE  
22 WOULD NEVER GET HERE, MEA CULPA.

23 CHAIRMAN LO: DO I HAVE A FORMAL MOTION TO  
24 ADOPT THIS AS THE SENSE THIS COMMITTEE?

25 MS. CHARO: I MOVE TO GIVE UP.

1 DR. KIESSLING: SO MOVED.

2 DR. PRIETO: SECOND.

3 CHAIRMAN LO: DR. KIESSLING AND DR. PRIETO  
4 MOVED AND SECONDED. ANY ADDITIONAL COMMENT? AGAIN,  
5 INVITING MEMBERS OF THE PUBLIC. OKAY. ALL THOSE IN  
6 FAVOR SAY AYE. ANY NAYS? ANY ABSTENTIONS? SO IT'S  
7 UNANIMOUS THE SENSE OF THIS COMMITTEE.

8 MS. LANSING: I WOULD LIKE TO ADD THAT OUR  
9 SENSE OF HUMOR PERSISTED THROUGHOUT ALL OF THIS.  
10 THAT'S A REALLY GOOD SIGN OF A VERY HEALTHY WORKING  
11 GROUP.

12 CHAIRMAN LO: MY THANKS TO ALL OF YOU FOR  
13 HANGING IN THERE AND SORT OF SEEING THIS THROUGH TO A  
14 CONCLUSION, WHICH I THINK IS A GOOD ONE. I THINK THIS  
15 IS SOMETHING WE CAN BE PROUD OF.

16 MS. LANSING: THANKS TO OUR REPRESENTATIVE  
17 FROM THE PUBLIC WHO BROUGHT A LOT TO OUR ATTENTION.  
18 YOU DID A GREAT JOB.

19 CHAIRMAN LO: OKAY. HAVING DONE THAT, WE  
20 COULD JUST CONGRATULATE OURSELVES AND GO HOME, BUT I  
21 WOULD LIKE -- I WOULD LIKE, IF POSSIBLE, TO JUST PUSH  
22 ON TO THIS ONE OTHER THING ON THE COMPENSATION FOR  
23 ACTUAL LOST WAGES TO OOCYTE DONORS WHO ARE DONATING  
24 OOCYTES. AGAIN, BECAUSE WE GOT A NUMBER OF NEGATIVE  
25 COMMENTS ON THIS, DO WE WANT TO READDRESS OR NOT?

1 MS. LANSING: THEY'RE SAYING WE SHOULDN'T --

2 CHAIRMAN LO: THEY'RE SAYING WE SHOULDN'T  
3 COMPENSATE FOR LOST WAGES, PERIOD, JUST ONLY OTHER  
4 REASONABLE EXPENSES, TRANSPORTATION, CHILDCARE, MEALS.

5 DR. KIESSLING: WE ARE TALKING ABOUT THE  
6 PROPOSED LAW?

7 DR. PRIETO: WELL, THE PROPOSED LAW DOES  
8 STIPULATE THAT ACCORDING TO SB 1260. WELL, IT SAYS  
9 THESE CONCERNS ARE REFLECTED IN SB 1260, BUT THIS IS  
10 FROM THE CENTER FOR -- PRO-CHOICE ALLIANCE FOR  
11 RESPONSIBLE RESEARCH AND THE CENTER FOR GENETICS AND  
12 SOCIETY ON THEIR PAGE 2 UNDER THE PERMISSIBLE EXPENSES.  
13 THAT'S JUST THEIR RECOMMENDATION AGAINST INCLUDING  
14 ACTUAL LOST WAGES, WHICH SEEMS KIND OF COUNTERINTUITIVE  
15 TO ME, BUT I UNDERSTAND THEIR ARGUMENT. I DON'T KNOW  
16 IF EVERYONE HAS READ THIS OR YOU'RE READING NOW. I  
17 DIDN'T WANT TO READ THE WHOLE PARAGRAPH.

18 CHAIRMAN LO: THIS IS THEIR ARGUMENT. THERE  
19 ARE ARGUMENTS ON THE OTHER SIDE. NOT TO WOULD MAKE THE  
20 LEAST ECONOMICALLY -- THE WORST OFF ECONOMICALLY EVEN  
21 WORSE OFF IF THEY HAPPEN TO LOSE OUT ON COMPENSATION  
22 FOR LOST WAGES.

23 DR. PRIETO: WELL, THAT'S THEIR ARGUMENT,  
24 THAT THE LOWEST INCOME WOMEN ARE THE LEAST LIKELY TO BE  
25 ABLE TO RECOUP -- TO ACTUALLY TAKE A DAY OFF.

1                   CHAIRMAN LO:   STATISTICALLY, BUT THE WOMAN  
2   WHO ACTUALLY IS ABLE TO TAKE A DAY OFF, BUT HAS TO GIVE  
3   UP HER WAGES, BUT OTHERWISE WOULD REDUCE HER PAYCHECK  
4   AND SAY I LOST X DOLLARS, SHE LOSES THOSE X DOLLARS IF  
5   WE DON'T ALLOW HER TO BE COMPENSATED.   I THINK THE  
6   ARGUMENT IS THAT RICHER WOMEN WILL BE COMPENSATED BACK  
7   MORE, AND POORER WOMEN, MANY OF THEM WON'T GET  
8   COMPENSATED AT ALL BECAUSE THEY'RE HOURLY WAGE EARNERS  
9   OR UNCOMPENSATED.   BUT ONES THAT -- BUT THE POOR WOMEN  
10  WHO DO HAVE LOST WAGES WON'T GET ANYTHING, AND THEY MAY  
11  BE -- LOSS OF THOSE WAGES MAY MEAN MORE TO THEM THAN  
12  THE LOSS OF THE HIGHER WAGES TO A MORE AFFLUENT WOMAN.

13                   MS. LANSING:   LET ME ASK YOU A QUESTION.  
14  THERE MUST BE SOME CAP ON THIS BECAUSE, SAY, YOU HAVE A  
15  PERSON WHO'S EARNING MILLIONS OF DOLLARS A YEAR, WE'RE  
16  CERTAINLY NOT GOING TO BE ABLE TO COMPENSATE THEM FOR  
17  THEIR LOST WAGES, AND WHICH MANY WOMEN TODAY ARE.   SO  
18  WHAT I'M REALLY TRYING TO SAY IS HOW DO YOU -- IS THERE  
19  A CAP ON THIS?

20                   DR. PRIETO:   I THINK, PRACTICALLY SPEAKING,  
21  WOMEN AREN'T GOING TO MAKE IT FAR IN THE SCREENING  
22  PROCESS.   THANK YOU FOR STOPPING BY TODAY.   WE'LL LET  
23  YOU KNOW.   WHEN IT LOOKS LIKE, YES, RECOUPING YOUR LOST  
24  WAGES FOR ONE DAY FOR A VERY HIGH EARNING WOMAN MAY BE  
25  TOLD JUST FOR PRACTICAL REASONS, WELL, THIS IS GOING TO

1 BE LIKE 20 PERCENT OF OUR GRANT.

2 MS. LANSING: SO THEN SHE WOULD HAVE TO SAY I  
3 DON'T WANT MY LOST WAGES.

4 MR. SHEEHY: I THINK WE HAD THE DISCUSSION  
5 LAST TIME, THE THINKING WAS ON A PRACTICAL MATTER, AS A  
6 PRACTICAL MATTER, THAT THE ESCRO OR IRB -- AS A  
7 PRACTICAL MATTER, THE PI WOULD CAP THE REIMBURSEMENT AS  
8 A PRACTICAL MATTER.

9 CHAIRMAN LO: THAT WOULD REDUCE THE INEQUITY.

10 MR. SHEEHY: IF MY MEMORY IS CORRECT, WE  
11 DECIDED AT THAT TIME NOT TO SET A CAP BECAUSE THE IRB  
12 OR THE SCRO OR THE PI WOULD SET THAT CAP.

13 MS. LANSING: SEE, THAT'S WHERE I WAS GOING.

14 MR. SHEEHY: THIS IS JUST IMPRACTICAL.

15 MS. LANSING: THAT'S WHAT I WAS GOING TO SAY.  
16 WE SHOULD PUT A SENTENCE IN, SEE, BECAUSE I DO BELIEVE  
17 THAT THE WOMAN WHO HAS LESS ECONOMIC MEANS WILL BE  
18 DETERRED FROM COMING IF SHE CANNOT RECOUP HER LOST  
19 WAGES, AND I THINK THAT WILL BE A PROBLEM. AND I'M  
20 MORE CONCERNED ABOUT THAT INEQUITY THAN I AM ABOUT A  
21 WOMAN OF SUBSTANTIAL MEANS BEING DETERRED BECAUSE SHE  
22 REALLY WILL SAY I DON'T NEED THIS MONEY AND I DON'T  
23 WANT IT. I'M GIVING IT BACK TO YOU.

24 SO MY FEELING IS THAT WE SHOULD SAY THAT  
25 THERE MUST BE SOME STATE CAP OR SOMETHING OR SOMETHING

1 THAT WE SHOULD SAY WE ARE TURNING OVER TO THEM TO CAP  
2 THIS, AND THAT'S WHAT IT WILL BE.

3 MR. SIMPSON: MAYBE I'M OUT OF ORDER. MY  
4 RECOLLECTION IS EXACTLY WHAT JEFF WAS SAYING. AND I  
5 THINK -- I WAS DIGGING FOR REGULATIONS. IT DOESN'T SAY  
6 THERE WILL BE. IT SAYS MAY BE, SO PRESUMABLY IT'S UP  
7 TO THE IRB WHETHER THEY'LL EVEN OFFER THAT BENEFIT OF  
8 REIMBURSEMENT FOR LOST WAGES. SO SPEAKING PERSONALLY,  
9 I'M A STRONG ADVOCATE OF REIMBURSEMENT AND ALLOWING  
10 THAT TO GO THROUGH. AGAIN, I THINK JEFF'S IS EXACTLY  
11 MY RECOLLECTION OF THE DISCUSSION THE LAST TIME.

12 MS. LANSING: MAYBE WE NEED TO CLARIFY.

13 DR. TAYLOR: I SUPPORT WHAT JEFF IS SAYING.  
14 I THINK THE IRB IS NOT GOING TO REALLY WANT TO BE  
15 USURPED ON THIS. I THINK EACH INDIVIDUAL PROGRAM IS  
16 LIKELY TO WANT TO SET SOME STANDARD AND THEY AREN'T  
17 ALWAYS EXACTLY THE SAME.

18 DR. KIESSLING: A REASONABLE REFERENCE FOR  
19 THIS IS JURY DUTY. AND PEOPLE ARE NOT COMPENSATED OR  
20 REIMBURSED FOR LOST WAGES FOR JURY DUTY. SOMEBODY HAS  
21 DECIDED WHAT THE STATE OR THE COUNTY CAN AFFORD FOR  
22 JURY DUTY. THE ONLY REASON I THINK WE GOT INTO THE  
23 WAGES ISSUE WHEN WE DISCUSSED THIS BEFORE, AND JUST  
24 TALKING ABOUT REIMBURSEMENT AT ALL WAS WONDERFUL, WAS  
25 THE IDEA THAT YOU DIDN'T WANT SOMEONE WHO WAS A VERY

1 LOW-INCOME PERSON TO DO THIS FOR A HIGHER WAGE THAN SHE  
2 WOULD NORMALLY GET FROM HER JOB.

3 NOW, THAT, WHEN YOU THINK ABOUT IT, IS KIND  
4 OF A SMALL CONCERN. EVERY AREA HAS A MEDIAN INCOME, SO  
5 YOU COULD CERTAINLY FIGURE OUT WHAT THE MEDIAN HOURLY  
6 INCOME IS FOR THAT AREA, AND YOU COULD OFFER SOME  
7 PERCENTAGE OF THAT OR USE THAT AS YOUR GUIDELINE FOR  
8 WHAT TO REIMBURSE.

9 DR. PETERS: COULD WE JUST TAG IT TO WHATEVER  
10 JURIES DO?

11 DR. KIESSLING: JURIES KIND OF HAVE A DAILY.  
12 IT'S DIFFERENT, BUT IT IS SORT OF A PUBLIC SERVICE  
13 IDEA. AND THE ONLY REASON TO NOT ESTABLISH A BLANKET  
14 PAYMENT FOR DONORS, WHICH IS WHAT WE'VE DONE IN BOSTON,  
15 AN HOURLY WAGE, WE ARRIVED AT AN HOURLY WAGE BECAUSE WE  
16 ASKED TEN MEN WHAT SOMEBODY WOULD HAVE TO PAY THEM TO  
17 INJECT THEMSELVES WITH HORMONES TWICE A DAY. WE CAME  
18 UP WITH VERY HIGH NUMBERS FROM THESE GUYS, MEN. WHAT  
19 WOULD IT TAKE, HOW MUCH WOULD YOU HAVE TO BE PAID TO  
20 GIVE YOURSELF A SHOT TWICE A DAY?

21 SO THE CONCERN HERE IS FINANCIAL INDUCEMENT,  
22 AND I THINK EACH IRB, IF THEY'RE GUIDED TO SIMPLY COME  
23 UP WITH THEIR STANDARD ACCORDING TO A MEDIAN WAGE,  
24 YOU'RE NOT GOING TO GET INVOLVED WITH A MEDIAN WAGE FOR  
25 THAT AREA. YOU'RE NOT GOING TO GET INVOLVED WITH

1 OVERCOMPENSATION CONCERNS.

2 MR. SHEEHY: WELL, I JUST -- I THINK ALTA IS  
3 ABOUT TO MAKE THE SAME COMMENT. IF WE SET ANYTHING, IT  
4 BECOMES COMPENSATION. THERE HAS TO BE ACTUAL LOST  
5 WAGES, OR WE VIOLATE THE LAW.

6 MS. CHARO: I ALSO JUST -- I REMEMBER --  
7 FIRST OF ALL, I THINK MR. SIMPSON IS CORRECT IN HIS  
8 MEMORY OF WHAT WAS GOING ON. PAT KING TALKED ABOUT THE  
9 VALUE OF HAVING A CAP. WE WENT THROUGH THIS  
10 CONVERSATION, AND THE JURY DUTY ANALOGY WAS USED,  
11 ALTHOUGH I'M NOT COMPLETELY COMFORTABLE WHETHER IT WAS  
12 JURY DUTY AS A MANDATORY THING, AND IT IS A PUBLIC  
13 SERVICE AND THIS IS ALTRUISTIC. MY SENSE OF IT IS THAT  
14 IF WE WRITE IN SOME CAP IN REGULATION, THAT IS THE END  
15 OF THE STORY. AND IT BOTH BECOMES A CEILING AND A  
16 FLOOR; THAT IS, I THINK IT'S GOING TO CREATE PRESSURE  
17 TO OFFER COMPENSATION UP TO WHATEVER AMOUNT WE IDENTIFY  
18 AS MUCH AS IT WILL OPERATE AS A CEILING ON THE AMOUNT  
19 THAT YOU CAN OFFER.

20 AND CONSISTENT WITH WHAT JEFF SAID, IF WE  
21 SIMPLY SAY REIMBURSEMENT IS PERMISSIBLE, BUT NOT  
22 REQUIRED, FOR ACTUAL OUT-OF-POCKET LOST WAGES, IT WILL  
23 NOT ONLY BE THE IRB'S AND ESCRO'S THAT ARE GOING TO  
24 HAVE THE OPPORTUNITY TO SAY DO WE WANT TO CAP FOR THIS,  
25 BUT IT'S GOING TO BE THE CIRM TECHNICAL PEOPLE WHO ARE



1 DECIDING WHETHER OR NOT TO FUND THE GRANT BECAUSE IT  
2 AFFECTS HOW MUCH MONEY THE GRANT IS GOING TO COST.

3 SO THERE ARE GOING TO BE LOTS OF  
4 OPPORTUNITIES FOR PEOPLE TO SAY I THINK WE NEED A CAP  
5 HERE, AND I THINK WE NEED A CAP THERE. LET'S CAP IT AT  
6 WHATEVER STATE LEGISLATORS GET, THEIR PER DIEM. THAT  
7 SEEMS TO BE A GOOD NUMBER TO USE, WHATEVER NUMBER THEY  
8 WANT TO REACH FOR. BUT I DON'T KNOW THAT WE NEED TO  
9 WRITE IT INTO A REGULATION THAT TRANSCENDS ALL THOSE  
10 BODIES OF DECISION-MAKING.

11 CHAIRMAN LO: TO TRY AND FOLLOW UP WITH THESE  
12 COMMENTS, ANOTHER OPTION IS TO USE ALTA'S LANGUAGE AND  
13 THEN GO ON TO SAY THE IRB SHALL CAP PAYMENTS FOR LOST  
14 WAGES TO AVOID UNDUE INDUCEMENT. ESTABLISH THE  
15 PRINCIPLE, WE DON'T WANT UNDUE INDUCEMENT, BUT CLEARLY  
16 GIVES THE AUTHORITY, REAFFIRMS THE IRB'S AUTHORITY TO  
17 DETERMINE WHAT IS --

18 MS. CHARO: ARE YOU SUGGESTING THAT  
19 REIMBURSEMENT FOR LOST WAGES COULD EVER BE AN  
20 INDUCEMENT, BERNIE? IS THAT WHAT YOU REALLY WANT TO  
21 SAY?

22 DR. OLDEN: I HAVE A FUNDAMENTAL QUESTION.  
23 DO WE HAVE A REQUIREMENT TO THE GRANT APPLICATION THAT  
24 THE APPLICANT DEMONSTRATE TO THE REVIEW COMMITTEE OR  
25 THE ADMINISTRATION OF THE PROGRAM THAT THEY HAVE IN

1 PLACE A PLAN THAT WILL ENSURE DIVERSITY IN TERMS OF  
2 THEIR SAMPLE SELECTION BECAUSE THAT MAY GET AROUND  
3 THIS? BECAUSE I WOULDN'T WANT TO LEAVE IT UP TO AN  
4 INVESTIGATOR UNLESS HE OR SHE HAD DEMONSTRATED IN THE  
5 APPLICATION THAT THEY HAD A PLAN THAT WOULD REALLY  
6 ENSURE THE INCLUSION OF PERSONS FROM LOW SOCIOECONOMIC  
7 BACKGROUND. IF THAT'S IN PLACE, THEN I THINK WE CAN  
8 LEAVE IT UP TO THE INVESTIGATOR TO DECIDE.

9 CHAIRMAN LO: WE HAVE SOMETHING, BUT NOT  
10 QUITE AS SPECIFIC TO WHAT YOU JUST SAID. SO ON PAGE 17  
11 OF OUR HANDOUT THAT LISTS WHAT WENT OUT TO THE PUBLIC,  
12 IT'S ENTITLED "FAIRNESS AND DIVERSITY IN RESEARCH." WE  
13 SAY CIRM GRANTEES SHALL COMPLY WITH THE CALIFORNIA  
14 HEALTH RESEARCH FAIRNESS ACT, CALIFORNIA HEALTH AND  
15 SAFETY CODE, BLAH, BLAH, INCLUSION OF WOMEN AND  
16 MINORITIES IN CLINICAL RESEARCH ACT.

17 NOW, I DON'T KNOW IF THAT SPECIFICALLY SAYS  
18 YOU'VE GOT TO DEMONSTRATE IN YOUR GRANT APPLICATION  
19 THAT YOU HAVE A PLAN TO ENSURE ADEQUATE REPRESENTATION.  
20 THAT'S ACTUALLY WHAT THE NIH REQUIRES IN THE LAST PART.  
21 YOU HAVE TO SHOW HOW YOU ARE GOING TO ACHIEVE  
22 DIVERSITY.

23 DR. OLDEN: IF THERE'S A LOGICAL REASON FOR  
24 YOU CAN'T ACHIEVE IT OR FROM A SCIENTIFIC POINT OF VIEW  
25 IT'S NOT DESIRABLE TO ACHIEVE IT, THEN YOU HAVE TO MAKE

1 THAT ARGUMENT. AND WE'LL SOMETIME ACCEPT IT.

2 MR. LOMAX: WHAT THAT LAW SAYS IS IF YOU DO  
3 NOT ALREADY COMPLY WITH THE NIH 1993 RULE ON DIVERSITY,  
4 THEN IT ESSENTIALLY MANDATES THE DEVELOPMENT OF  
5 SOMETHING THAT'S SUBSTANTIALLY SIMILAR. SO IT'S  
6 PEGGING IT TO THE NIH POLICY.

7 CHAIRMAN LO: GEOFF, DO YOU ALSO WANT TO TELL  
8 US WHAT THE BRITISH, THE NEW UK POLICY IS ON  
9 REIMBURSEMENT -- I'M SORRY -- REIMBURSEMENT FOR LOST  
10 WAGES?

11 MR. LOMAX: YES. EARLIER THIS YEAR WE HAD A  
12 CONCERN ACTUALLY WITH THE UK STEM CELL LINE BECAUSE  
13 THERE WAS -- INITIALLY THEY HAD A FLAT RATE THEY WERE  
14 PAYING. AND THEIR REGULATIONS SAID YOU CAN PAY A  
15 CERTAIN AMOUNT EVEN THOUGH IT WAS A VERY SMALL AMOUNT,  
16 15 £. THEY'VE NOW RESCINDED THAT AUTHORIZATION TO GIVE  
17 SOMEBODY A PAYMENT FOR PARTICIPATING, AND THEY NOW DO  
18 AUTHORIZE PAYMENT FOR DOCUMENTED LOSS OF EARNINGS, SO  
19 IT'S SIMILAR TO OURS. IT'S ACTUAL LOST WAGES. THEY  
20 USE THE TERM "DOCUMENTED," AND THEY DO SET A CAP ON A  
21 DAILY MAXIMUM OF ROUGHLY ABOUT \$80, 55 £, AND THEN THEY  
22 CREATE AN OVERALL LIMIT FOR TOTAL COMPENSATION OF --  
23 TOTAL REIMBURSEMENT FOR 250 £ FOR EACH COURSE -- FOR  
24 EACH CYCLE OF EGG DONATION.

25 MS. LANSING: I DO THINK IN ORDER TO PROTECT

1 THE LOW-INCOME WOMAN, WE NEED TO DO SOMETHING. I THINK  
2 THAT I LIKE, I GUESS, WHAT JEFF SAID AND JOHN SAID,  
3 THAT WE BASICALLY SAY THAT, YOU KNOW, WE'RE GOING TO  
4 REIMBURSE WAGES WITH A CAP, WHICH WILL BE DETERMINED BY  
5 THE IRB'S, YOU KNOW, AND WE'RE GOING TO LEAVE IT TO  
6 THEM. AND, THEREFORE, SOMEBODY WHO IS DISADVANTAGED  
7 WILL NOT BE DISADVANTAGED IN DONATING THEIR EGGS.

8 DR. TAYLOR: DON'T YOU THINK THE CAP -- I  
9 DON'T SEE THE BENEFIT THE CAP PROVIDES. IT PROVIDES A  
10 TARGET FOR PEOPLE WHO FEEL THE ORIGINAL LANGUAGE WAS SO  
11 RESTRICTIVE ON ANY SORT OF COMPENSATION. I DON'T  
12 REALLY SEE -- I DON'T BELIEVE THAT AN IRB IS GOING TO  
13 LOW-BALL THE SUBJECTS. AND I'M JUST KIND OF CONCERNED  
14 ABOUT THE POLITICAL FALLOUT OF ESTABLISHING ANY KIND OF  
15 NUMERICAL CAP OR FLOOR OR WHATEVER YOU DECIDE IT IS.

16 MS. LANSING: WELL, I'M EQUALLY WORRIED THAT  
17 THEY WILL REJECT PEOPLE WHOSE INCOME IS TOO HIGH. DO  
18 YOU KNOW WHAT I MEAN? THIS IS SORT OF LIKE AN  
19 EQUALIZER. IT'S LIKE JURY DUTY, AND I ACTUALLY THINK  
20 THAT'S A MODEL THAT SERVES US WELL. DO YOU KNOW?

21 DR. TAYLOR: BUT IT'S A VOLUNTARY. IT'S NOT  
22 A MANDATED REIMBURSEMENT FOR LOST WAGES. IN YOUR  
23 MILLIONAIRE EXAMPLE --

24 CHAIRMAN LO: MILLIONAIRE, IF YOU HAD A CAP,  
25 A MILLIONAIRE WOULD ONLY GET A CAP, NOT HER ACTUAL LOST

1 WAGES. THEREFORE, YOU DECREASE THE DISCREPANCY BETWEEN  
2 WHAT SHE WOULD GET PAID AND WHAT THE POOR MINIMAL WAGE  
3 WOMEN GET PAID FOR THE SAME WORK.

4 DR. TAYLOR: I ABSOLUTELY AGREE THAT SHOULD  
5 HAPPEN, BUT I'M JUST NOT SURE THAT IT NEEDS TO BE  
6 SPECIFIED.

7 MR. SHEEHY: I JUST THINK WE DID A GREAT JOB,  
8 AND I WOULDN'T CHANGE THE LANGUAGE. I THINK THE GOAL  
9 HERE OF THIS OBJECTION IS ZERO, NO REIMBURSEMENT AT  
10 ALL. SO WE CAN -- I DON'T THINK THAT THIS IS A -- I  
11 THINK WE WENT THROUGH ALL OF THIS ONCE. I THINK WE  
12 CAME UP WITH THE IDEAL SOLUTION. WE ARE STARTING TO  
13 UNWIND THAT, AND WE'RE STARTING TO FORGET SOME OF THE  
14 CONSIDERATIONS WE HAD, AND SOME OF THESE I THINK WE CAN  
15 REJECT BECAUSE I DON'T BELIEVE THE GOAL HERE -- I THINK  
16 THE GOAL IS EXPLICIT, THAT NO REIMBURSEMENT IS  
17 ACCEPTABLE.

18 MS. LANSING: WILL YOU READ WHAT OUR LANGUAGE  
19 IS NOW AGAIN ONE MORE TIME?

20 MR. LOMAX: LET ME GO AHEAD AND READ THE  
21 DEFINITION, BECAUSE I THINK THAT'S THE IMPORTANT TERM,  
22 THE DEFINITION OF PERMISSIBLE EXPENSES. SO WHAT IT  
23 SAYS IS "YOU MAY COMPENSATE THE DONOR FOR PERMISSIBLE  
24 EXPENSES. PERMISSIBLE EXPENSES MEANS NECESSARY AND  
25 REASONABLE COSTS DIRECTLY INCURRED AS A RESULT OF A

1 DONATION OR PARTICIPATION IN RESEARCH ACTIVITIES.  
2 PERMISSIBLE EXPENSES MAY INCLUDE, BUT ARE NOT LIMITED  
3 TO COSTS ASSOCIATED WITH TRAVEL, HOUSING, CHILDCARE,  
4 MEDICAL CARE, HEALTH INSURANCE, AND ACTUAL LOST WAGES."

5 MS. LANSING: AND IT MAY INCLUDE, WHICH IS  
6 WHAT YOU SAY. IT DOESN'T HAVE TO, SO I THINK YOU'RE  
7 RIGHT.

8 MS. CHARO: AND THE WORD "REASONABLE" IS ALSO  
9 IN THAT FIRST LINE, WHICH IS THE INVITATION FOR LOTS OF  
10 DISCUSSION ABOUT CAPS.

11 MS. LANSING: THAT'S FINE.

12 CHAIRMAN LO: AGAIN, THE IDEA IS WE DON'T  
13 WANT TO REVISIT SOMETHING WE ALREADY RESOLVED UNLESS  
14 THERE'S A COMPELLING NEW ARGUMENT THAT WE HAVEN'T  
15 THOUGHT OF.

16 MS. LANSING: WE DID REVISIT IT.

17 CHAIRMAN LO: SO NOW I'M GOING TO SAY  
18 EVERYTHING ELSE WE HAVEN'T TALKED ABOUT FALLS BELOW  
19 THAT THRESHOLD OF OTHER THINGS ON THE LIST WE ALREADY  
20 HAD TALKED, EITHER THERE ARE THINGS IN THE B SECTION WE  
21 HAVE TALKED ABOUT, AND WE CONSIDERED THE EXACT ARGUMENT  
22 THAT WAS RAISED IN THE PUBLIC STATEMENT, AND WE DECIDED  
23 AGAINST IT. RATHER THAN TO REPEAT THE DISCUSSION WE  
24 HAD, I THINK WE SHOULD JUST SAY, THANK YOU. WE  
25 CONSIDERED THAT AND THOUGHT ABOUT IT, AND WE CAME DOWN

1 THE OTHER WAY.

2 THE OTHER COMMENTS WHICH I DON'T THINK WE  
3 DISCUSSED WHICH ARE REALLY YOU COULDN'T HAVE MEANT TO  
4 SAY WHAT YOU SAID BECAUSE THAT DOESN'T DO WHAT YOU WERE  
5 INTENDING TO DO. WHAT YOU REALLY MEANT TO SAY WAS  
6 THIS. AND IT SEEMS LIKE JUST A TECHNICAL LANGUAGE  
7 CORRECTION I THINK THAT I WOULD ORDINARILY DEFER TO  
8 STAFF.

9 IF YOU HAVE ANY OBJECTION TO ANY OF THIS, I'D  
10 LIKE YOU TO READ THEM ALL THROUGH, BUT I THINK WE DON'T  
11 NEED GO THROUGH THEM ONE BY ONE AT THIS POINT.

12 MR. LOMAX: I WOULD AT THIS POINT SUGGEST  
13 THAT WE GO AHEAD AND MAKE A MARKUP COPY OF THE  
14 REGULATIONS REFLECTING THE DECISIONS MADE HERE TODAY IN  
15 ADDITION TO WHAT WE DESCRIBED AS THE MORE TECHNICAL  
16 COMMENTS AND MAKE THOSE REVISIONS AVAILABLE BOTH TO THE  
17 WORKING GROUP AND THE PUBLIC AND JUST GO OUT. IT WILL  
18 BE DIRECTLY SENT OUT TO YOU ALL AND MADE AVAILABLE TO  
19 THE PUBLIC. AND YOU ALL WOULD HAVE HAD A CHANCE TO  
20 REVIEW THEM AND GET BACK IF THERE WAS ANYTHING THAT  
21 CAME UP THAT SEEMED PROBLEMATIC.

22 CHAIRMAN LO: AND THESE WILL BE POSTED AS  
23 SOON AS WE CAN GET THEM TECHNICALLY DONE SO THAT WE  
24 MEET THE 15-DAY PUBLIC COMMENT PERIOD FOR ANY REVISIONS  
25 TO WHAT WE HAVE PROPOSED.

1 MR. TOCHER: THAT'S RIGHT.

2 DR. KIESSLING: GEOFF, WE'RE GOING TO GET A  
3 NEW COPY OF THIS, NOT YOUR SUMMARY?

4 MR. LOMAX: THE ACTUAL TEXT. WHAT I'M  
5 PROPOSING AT THIS POINT, AND, SCOTT, I THINK WE CAN DO  
6 THIS. WE'LL DO SORT OF TWO COPIES, ONE WHICH WILL BE A  
7 CLEAN COPY, BUT WE'D LIKE TO DO SOMETHING ON THE ORDER  
8 OF A TRACK CHANGE COPY. IF WE HAVE THE ENERGY AND THE  
9 MOUSE STRENGTH LEFT, WE'LL TRY TO DO THE  
10 STRIKE-THROUGHS AND DOUBLE UNDERLINES JUST SO YOU SEE  
11 THE CHANGES.

12 CHAIRMAN LO: DO TRACK CHANGES AND THEN TAKE  
13 THE CHANGES AND SHOW US A CLEAN COPY AND WE CAN FIGURE  
14 OUT THE REST.

15 ALL RIGHT. ARE THERE ANY BURNING ISSUES THAT  
16 ANY MEMBER OF THE COMMITTEE WISHES TO BRING UP? ANY  
17 BURNING ISSUES THAT ANY MEMBER OF THE PUBLIC WANTS TO  
18 BRING UP?

19 MR. SIMPSON: JOHN SIMPSON FROM THE  
20 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I JUST  
21 WANTED TO COMMEND YOU ALL FOR YOUR VERY LONG PRODUCTIVE  
22 DAY. I THOUGHT IT WAS AN EXCELLENT MEETING. THANK  
23 YOU.

24 MS. LANSING: I ALSO WANT TO THANK YOU  
25 BECAUSE YOU ALWAYS ARE SO TERRIFIC AND SO RATIONAL AND



1 SO HELPFUL .

2 CHAIRMAN LO: ANN HAD A QUESTION ABOUT WHERE  
3 DO WE GO FROM HERE. IT DEPENDS ON OUR BUDGET, WHICH IS  
4 UP IN THE AIR.

5 MR. LOMAX: I WAS ASKED TO PROPOSE -- PROJECT  
6 A MEETING SCHEDULE THROUGH THE FIRST HALF OF THIS  
7 FISCAL YEAR, WHICH WOULD BE JULY THROUGH DECEMBER, SO  
8 SECOND THE HALF OF 2006. I RECOMMENDED ONE MEETING  
9 LIKE THIS WHERE FOLKS ARE TOGETHER AND THEN ONE  
10 TELEPHONE MEETING. AND THERE WAS A METHOD -- THERE WAS  
11 A LOGIC THERE, AND IT'S ESCAPED ME RIGHT NOW.

12 I THOUGHT THERE WAS ONE FINAL POINT IN THE  
13 PROCESS WHERE WE NEEDED -- I KNOW WHAT IT IS. BECAUSE  
14 WE HAVE PROMULGATED, WE PUT INTO PLAY THE FETAL TISSUE  
15 REGULATION, WHICH IS NOW PUT FORWARD AS A 270-DAY  
16 TEMPORARY REGULATION, WE'RE GOING TO HAVE TO FINALIZE  
17 OUR FETAL TISSUE RULES. SO THERE'S SOME VERY PRACTICAL  
18 REASONS TO GET TOGETHER IN TERMS OF OUR NEXT CYCLE OF  
19 REGULATIONS, AND THAT WAS THE IDEA OF GETTING TOGETHER  
20 IN PUBLIC, AND THEN RESERVING SOME ADDITIONAL MEETING  
21 TIME BY PHONE IN THE EVENT THAT WE NEED TO FOLLOW UP  
22 AGAIN ON THAT REGULATION AS IT MOVES THROUGH -- WHEN IT  
23 GETS TO THIS STAGE, THE STAGE WHERE IT'S BEEN NOTICED  
24 AS A FINAL REG AND THAT WE WANT TO GET PUBLIC COMMENTS.  
25 THAT WILL COVER US THROUGH HOPEFULLY THE END OF THE

1 YEAR WITH TWO CYCLES OF REGULATIONS, IF ALL GOES WELL,  
2 BOTH THROUGH THIS AND WE MAKE IT THROUGH THE FETAL  
3 TISSUE REGULATION.

4 CHAIRMAN LO: PROJECTING EVEN FURTHER THAN  
5 THAT, SHERRY CONTINUALLY REMINDS US VERY WISELY THAT  
6 THIS IS GOING TO BE AN ONGOING PROCESS. THERE WILL BE  
7 NEW ISSUES THAT EMERGE, NEW SCIENTIFIC THINGS THAT NEED  
8 TO CONSIDER THINGS WE'VE DONE.

9 A PARTICULAR SET OF ISSUES THAT I'M VERY  
10 CONCERNED ABOUT IS THE DOWNSTREAM CLINICAL TRIALS THAT  
11 WE HOPE WILL BE FORTHCOMING. AND IT STRIKES ME THAT  
12 THERE'S BOTH TREMENDOUS EXCITEMENT AND HOPE, BUT ALSO A  
13 LOT OF CONCERNS ABOUT WHEN IS THE PROPER TIME TO DO THE  
14 FIRST STUDIES WITH HUMANS WITH CIRM FUNDING,  
15 PROTECTIONS IN TERMS OF MISCONCEPTIONS ABOUT THE  
16 PERSONAL BENEFITS OF RESEARCH AND THE INFORMED CONSENT  
17 PROCESS. AND I THINK IT WOULD BE IMPORTANT TO TRY AND  
18 ANTICIPATE THOSE EVENTS COMING UP SO THAT WE CAN HAVE  
19 GOOD REGULATIONS IN PLACE WHEN WE GET APPLICATIONS FOR  
20 FUNDING. THAT, OF COURSE, WILL DEPEND ON WHAT OUR CIRM  
21 BUDGET LOOKS LIKE.

22 OKAY. HAVING SAID THAT, I PERSONALLY WANT TO  
23 THANK ALL OF YOU WHO STAYED THROUGH HERE. I THINK IT  
24 WAS A VERY USEFUL AND PRODUCTIVE MEETING, AND WE CAN  
25 COME OUT WITH EVEN BETTER GUIDELINES THAN WERE PROPOSED

1 BEFORE. I'M PARTICULARLY GRATEFUL FOR YOU ALL STICKING  
2 TOGETHER AND COMING UP WITH THINGS THAT WE ALL CAN LIVE  
3 WITH.

4 DR. PETERS: THANKS TO SHERRY AND BERNIE.

5 (APPLAUSE.)

6 MS. LANSING: THANKS TO BERNIE. BERNIE IS AN  
7 EXTRAORDINARY LEADER, AND I'M VERY, VERY GRATEFUL TO  
8 JUST SIT NEXT TO HIM. I JUST WANT TO THANK ALL OF YOU,  
9 AND IT REALLY HAS BEEN VERY STIMULATING. AND I THINK  
10 WE'VE DONE GREAT WORK, AND WE DON'T HAVE TO SAY GOODBYE  
11 BECAUSE WE'RE GOING TO SEE EACH OTHER AGAIN, WHICH I  
12 HAVE ACTUALLY COME TO LOOK FORWARD TO.

13 (THE MEETING WAS THEN CONCLUDED AT 4:33  
14 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

LUXE HOTEL  
11461 SUNSET BOULEVARD  
LOS ANGELES, CALIFORNIA  
ON  
MAY 3, 2006

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152  
BARRISTER'S REPORTING SERVICE  
1072 S.E. BRISTOL STREET  
SUITE 100  
SANTA ANA HEIGHTS, CALIFORNIA  
(714) 444-4100